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PRESIDENT'S FISCAL YEAR 2014 HEALTH CARE PROPOSALS

HEARING

BEFORE THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

ONE HUNDRED THIRTEENTH CONGRESS

FIRST SESSION

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PRESIDENT'S FISCAL YEAR 2014 HEALTH CARE PROPOSALS

WEDNESDAY, APRIL 17, 2013

U.S. SENATE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 10:10 a.m., in room SD–215, Dirksen Senate Office Building, Hon. Max Baucus (chairman of the committee) presiding.

Present: Senators Cantwell, Nelson, Menendez, Cardin, Bennet, Casey, Hatch, Grassley, Crapo, Roberts, Thune, Isakson, Portman, and Toomey.

Also present: Democratic Staff: Mac Campbell, General Counsel; David Schwartz, Chief Health Counsel; and Matt Kazan, Health Policy Advisor. Republican Staff: Chris Campbell, Staff Director; Kim Brandt, Chief Healthcare Investigative Counsel; and Stephanie Carlton, Health Policy Advisor.

OPENING STATEMENT OF HON. MAX BAUCUS, A U.S. SENATOR FROM MONTANA, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. The committee will come to order.

Warren Buffett once said, "Price is what you pay. Value is what you get." This morning we are here to discuss the health care proposals in the President's fiscal year 2014 budget. As we do, we must determine the value in what we are paying. Specifically, I would like to focus on the value of Medicare and Medicaid. These programs touch the lives of more than 100 million Americans, nearly 1 in every 3 citizens.

I also want to examine the progress the administration has made in implementing the health reform law. If the administration implements it correctly, millions more Americans will gain access to health care next year as a result of the law. These programs fall under the purview of our witness this morning, Secretary Kathleen Sebelius, and the President's budget affects all of these programs.

I am sure you are quite busy, Madam Secretary. In just 167 days, millions of Americans will begin enrolling in health insurance plans in their State's marketplace. Time is short. You need to use each of these days to work with States to make sure the marketplaces are up and running, ready to help uninsured Americans access affordable coverage.

The President's budget requested a total of $5.2 billion for program management at the Centers for Medicare and Medicaid Services. Of this, $1.5 billion will be devoted to establishing and supporting the health insurance marketplaces.

I am concerned that not every State, including Montana, will have an insurance marketplace established in time. I want to hear how the money requested in the budget will be used to ensure those marketplaces will be ready to go on Day 1. The President's budget also requests $554 million for outreach and education for the health and insurance marketplaces.

For the marketplaces to work, people need to know about them. People need to know their options, how to enroll. I would like to hear the administration's outreach plan leading up to the enrollment period which begins October 1st. What has been done? I want these new marketplaces to be simple and successful.

I think it would be good that small businesses be able to focus on job creation, not confusion. More importantly, I want to know the plan moving forward to better communicate the benefits of the Affordable Care Act. I am concerned that lack of clear information is leading to misconceptions and misinformation.

People generally dislike what they do not understand. I hear from people on the ground in Montana that they are confused about the law. People are worried about the impacts of new rules and how marketplaces will affect their families and businesses. I especially hear that from small businesses in Montana. They just do not know what to do.

I reached out to Steph Larsen, who works in Montana with the Center for Rural Affairs. She has been traveling across the State, talking to business groups and consumers about the new marketplaces. She reported that few people are attending the informational meetings, and those who are often express a lack of understanding about the marketplaces and what they offer. Steph told my staff, "There is a lot of misinformation about how all that is going to work."

This difficulty is compounded by the unknown as to what the marketplaces will look like. My constituents do not understand the role of tax credits, because they simply do not have enough information. The administration needs to do a better job.

And it is not just Montanans. There was a poll last month by the Kaiser Family Foundation that found that 57 percent of Americans say they do not have enough information about the law to understand how it will affect them.

The lack of clear information is leading people to turn to incorrect information. In fact, 40 percent of Americans thought the law establishes a government panel to make end-of-life decisions for people on Medicare. Forty percent thought that under the Kaiser poll. Of course, the law does not provide that.

The poll also found that 57 percent of Americans thought the law includes a public option. Of course, the law does not do that either. The administration's public information campaign on the benefits of the Affordable Care Act, I think, deserve a failing grade. We need to fix it.

The budget also offers belt-tightening measures to address the deficit. The President's budget proposes $379 billion in Medicare and Medicaid spending reductions. There are some proposals I agree with to cut our debt: for instance, wealthy beneficiaries should pay higher premiums.

Also, we should not pay private plans offering Medicare benefits at a higher rate than traditional Medicare. And efforts to root out fraud must be strengthened, because every dollar invested in fighting fraud generates a 500-percent return in taxpayers' money received. That is good.

But there are other policies that concern me. I am concerned the proposed level of cuts to nursing homes may be too high and reduce access to care. I also have concerns over the President's chained CPI proposal. Moving to chained CPI not only impacts Social Security, it also reduces payments to Medicare providers and increases out-of-pocket costs for some seniors.

Cutting Social Security and Medicare will hit our seniors with a one-two punch. These chained CPI changes are on top of the $360 billion in cuts to Medicare that the President specified in his budget. Cutting our debt will require compromise. Everyone will need to pitch in, but we cannot balance the budget on the backs of America's seniors.

A plan to reign in our budget deficits cannot just be cuts to Medicare. It cannot just be a package of tax increases. We need a balanced approach that is fair to all. The administration's budget also recognizes the need to work with Congress to reauthorize the Temporary Assistance to Needy Families, otherwise known as TANF.

This program is a vital lifeline for our Nation's poorest families. I look forward to working with my Finance Committee colleagues to update the TANF program so that it is a more efficient job creator and a pathway out of poverty.

I am happy the budget makes an investment of $5.9 billion in early learning, including child care. This will allow us to make sure over 100,000 more kids start off on the road to success with early education. Montana families understand the value of good education in maintaining our responsibilities as parents and neighbors.

Secretary Sebelius, as we think about these issues and their effect on the budget, let us remember Mr. Buffett's advice. While the price is what we see in the budget, the value of what we receive is what matters.

[The prepared statement of Chairman Baucus appears in the appendix.]

The CHAIRMAN. Senator Hatch?

OPENING STATEMENT OF HON. ORRIN G. HATCH, A U.S. SENATOR FROM UTAH

Senator HATCH. Well, thank you, Mr. Chairman. Thank you for scheduling today's hearing. Secretary Sebelius, we want to thank you for taking time to come here to speak to us today.

Last week, the President released his proposed budget for fiscal year 2014. Although the budget was 65 days late, it does not appear that the administration used that extra time to find ways to address the critical problems facing our country.

Perhaps most significantly, the President's budget fails to address the fundamental challenge of health care entitlement spending in any significant way. What this document lacks in courage, it more than makes up for in the same partisan rhetoric and policies.

Keep in mind, CBO Director Doug Elmendorff has stated that our health care entitlements, Medicare and Medicaid, are our "fundamental fiscal challenge." Apparently, if this budget is any indication, the administration is not interested in taking up this challenge.

Under the President's budget, Medicare and Medicaid spending will reach nearly $11 trillion over the next decade. Annual mandatory health spending will nearly double, from $771 billion in 2013 to $1.4 trillion in 2023. That is, if their numbers are right. Although we are projected to spend nearly $7 trillion on Medicare over the next 10 years, the Hospital Insurance trust fund will continue to run significant deficits.

According to the 2012 Medicare trustees' report, the trust fund has $5.3 trillion in unfunded liabilities, and it is expected to be insolvent by the year 2024. Under this budget, the fund will continue on its path to insolvency.

The budget also fails to address many problems facing Medicaid, even though we will be spending more than $4 trillion on that program over the next 10 years. Under this budget, Federal Medicaid spending as a percent of GDP will increase by 25 percent, from 1.6 percent to 2 percent over the next decade, thanks to the expansion of the program courtesy of Obamacare.

It is unacceptable that a program that is the biggest line item in most State budgets and is crowding out essential spending in both education and public safety is barely addressed. All told, we will spend more than $22 trillion over the next 10 years on our major entitlement programs: Medicare, Medicaid, and of course Social Security.

The President's budget would reduce that amount by only $413 billion, or roughly 1.8 percent. No one seriously disputes that entitlement spending is the main driver of our debts and deficits, yet for the most part this budget has opted to ignore that reality and kick the proverbial can even further down the road.

These programs need serious structural reforms if they are going to be around for future generations. Entitlement reform is one of the fundamental challenges of our time. It will require a united effort from members of both parties.

Sadly, this budget fails to show this much-needed courage. I hope that we all will be willing to come to the table on serious structural reforms to our entitlement programs. I believe the President wants to do the right thing. What we need now is action. As you know, on January 1st I went to the Senate floor and unveiled five bipartisan entitlement reform proposals, five structural reforms to Medicare and Medicaid that have been supported by both Republicans and Democrats in the recent past.

I have put these ideas forward in hopes of starting a bipartisan conversation on entitlement reform. I have shared these proposals with the President, and I am ready and willing to work with him on solutions to these problems.

Secretary Sebelius, I will look forward to talking with you about these critical issues, and I want to thank you once again for being here, and I want to thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

[The prepared statement of Senator Hatch appears in the appendix.]

The CHAIRMAN. Welcome, Secretary Sebelius. We appreciate you coming here. You have a big job, and we wish you the very best. Your full statement will be in the record. Just tell us what you think, and let her rip.

STATEMENT OF HON. KATHLEEN SEBELIUS, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Secretary SEBELIUS. Good morning. Thank you, Chairman Baucus, Ranking Member Hatch, and members of the committee. I appreciate the opportunity to be with you today to discuss the President's 2014 budget for the Department of Health and Human Services.

This budget supports the overall goals of the President's budget by strengthening our economy and promoting middle-class job growth. It ensures that the American people will continue to benefit from the Affordable Care Act.

It will provide much-needed support for mental health services and will take steps to address the ongoing tragedy of gun violence. It strengthens education for our children during their critical early years to help ensure they can succeed in a 21st-century economy. It secures America's leadership in health innovation so that we remain a magnet for the jobs of the future. It helps reduce the deficit in a balanced, sustainable way.

I look forward to answering the members' questions about the budget, but first I would like to briefly cover a few of the highlights.

The Affordable Care Act, signed into law in March of 2010, is already benefitting millions of Americans. Our budget makes sure we can continue to implement the law. By supporting the creation of new health insurance marketplaces, the budget will ensure that, starting next January, Americans in every State will be able to get quality insurance at an affordable price.

Now, our budget also addresses another issue that has been on all of our minds recently: mental health services and the ongoing epidemic of gun violence. I know, Mr. Chairman, that the Senate later today will deal with legislation around keeping dangerous individuals from getting their hands on a gun.

As a Secretary of Health, a mother, and a new grandmother, I hope that the Senate gives very serious consideration to that common-sense bipartisan legislation that could indeed make this tragedy that is seen every day on streets across America less frequent than we see each and every day.

Now, we know that the vast majority of Americans who struggle with mental illness are not violent, but recent tragedies have reminded us of the staggering toll that untreated mental illness can take on our society. That is why our budget also proposes a major new investment to help ensure that students and young adults get the mental health care they need, including training of 5,000 additional mental health professionals to join our behavioral health workforce.

Our budget also supports the President's call to provide every child in America with access to high-quality early learning services. It proposes additional investments in new Early Head Start–Child Care Partnerships, and it provides additional support to raise the quality of child care programs and promote evidence-based home visiting for new parents.

Now, together, these investments will create long-lasting, positive outcomes for families and provide huge returns for the children and society at large. Our budget also ensures that America remains a world leader in health innovation. The budget's significant new investments in NIH will lead to new cures and treatments and help create good jobs.

The budget provides further support for the development and use of compatible electronic health record systems that have a huge potential for improving care coordination and public health. Even as our budget invests for the future, it helps to reduce the long-term deficit by making sure that programs like Medicare are put on a more stable fiscal trajectory.

Medicare spending per beneficiary grew at just four-tenths of 1 percent in 2012, thanks in part to the $800 billion in savings already included in the Affordable Care Act. The President's 2014 budget would achieve even more savings. For example, the budget will allow low-income Medicare beneficiaries to get their prescription drugs at lower Medicaid rates, resulting in savings of more than $120 billion over the next 10 years.

In total, the budget would generate an additional $370 billion in Medicare savings over the next decade on top of the savings already in the Affordable Care Act. To that same end, our budget also reflects our commitment to aggressively reducing waste across our Department.

We are proposing an increase in mandatory funding for a health care fraud and abuse control program, an initiative that saved the taxpayers nearly $8 for every $1 spent last year. We are investing in additional efforts to reduce improper payments in Medicare, Medicaid, and CHIP, and to strengthen our Office of Inspector General.

This all adds up to a budget guided by the administration's north star of a thriving middle class. It will promote job growth and keep our economy strong in the years to come, while also helping to reduce the long-term deficit.

Now, I know many of you have questions, and I am happy to take those now. Again, thank you for having me here today.

The CHAIRMAN. Thank you, Madam Secretary.

[The prepared statement of Secretary Sebelius appears in the appendix.]

The CHAIRMAN. I frankly have to leave this instant to take a phone call and will be right back. Senator Hatch, why don't you take over, and I will be right back?

Senator HATCH [presiding]. Secretary Sebelius, I am curious as to how your Department is funding overall efforts under the health law, now that much of the initial funding has been depleted. A quick review of the HHS budget in brief seems to suggest that you are diverting funds from other areas of the Department to put to-

wards implementation. Some estimates estimate as much as half a billion dollars might be moved from other portions of the budget.

Would you describe the authority under which you believe you have the ability to conduct such transfers, and whether or not you believe that Congress should be notified when these transfers occur?

Secretary SEBELIUS. Senator, we did request additional funding with the continuing resolution in 2013 and were not given additional resources by the U.S. Congress, although we have the duty to implement the law. So I have, for 2013, used both my transfer authority, which is statutorily in our budget, as well as the nonrecurring expense fund, for one-time IT costs, and a portion of funding for the prevention fund to use for outreach and education.

You heard Chairman Baucus describe the level of concern and questions in States around the country, and we want to make sure that Americans fully understand the benefits that are coming their way and the decisions that they can make. We have requested in the budget that is before you, in the 2014 budget, an additional $1.5 billion to fully implement the Affordable Care Act.

Senator HATCH. All right.

Federal Medicaid spending as a percentage of the economy, according to the budget, will increase by 25 percent over the next decade, driven by the Affordable Care Act expansions in long-term care spending. Now, that is more than $4 trillion over the next decade, and that is not even counting the trillions of dollars States will spend on Medicaid.

According to the National Governors Association, "Medicaid represents the single-largest portion of total State spending." Now, Madam Secretary, this budget backs off of prior proposals to lower spending on Medicaid, such as the blended FMAP rate and provider tax reductions.

Now, this is especially discouraging since there are bipartisan proposals that would have achieved significant Medicaid savings and improved patient care. In fact, your predecessor under President Clinton, Secretary of Health and Human Services Donna Shalala, said that Medicaid per capita caps mean "there are absolutely no incentives for States to deny coverage to a needy individual or to a family. It is a sensible way to make sure that people who need Medicaid are able to receive it."

Unfortunately, your fiscal year 2014 budget only proposes to save one-half of 1 percent in Medicaid, and it lacks any serious reforms to the Medicaid program. Now, my question would be, why does your budget completely fail to address one of the country's fundamental, most serious challenges?

Secretary SEBELIUS. Well, Senator Hatch, I think there is a very positive story to tell about Medicaid. Believe me, as a former Governor, I am dealing with my former colleagues and the CEOs of States around the country each and every day. Medicaid spending last year, between 2011 and 2012, actually decreased by almost 2 percent per beneficiary—decreased by 2 percent. That is virtually unheard of.

We are engaged in a series of what I would call very innovative strategies around the dual-eligible population, often those individuals whom you have just referred to in nursing homes, around

progress on reforming high-quality, lower-cost Medicaid health care delivery, working with States who are engaged in just exactly what States do the best, which is very innovative strategies looking at their overall health care spending.

So I think that the Medicaid story is one that is enormously positive, where Governors are very much engaged. We have been very pleased at the number of Governors who are interested in expanding their Medicaid population and providing health benefits for some of the lowest-income workers in a very cost-effective strategy.

Senator HATCH. Would you be open to work with us on bipartisan ideas to improve patient care and of course save money in the Medicaid program?

Secretary SEBELIUS. I would be happy to work with you and others on that.

Senator HATCH. Well, thank you so much.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

As you somewhat know, Madam Secretary, I am a bit of a Johnny One-Note on implementation of the law, especially with respect to sign-ups and exchanges, et cetera, and am very concerned that not enough is being done so far. Very concerned. When I am home, small businesses have no idea what to do, what to expect. They do not know what the affordability rules are. They do not know when penalties may apply. They just do not know.

I mean, I was talking to one CPA. He is not histrionic; he is being straight with me. He says, "Max, I just have to tell you, my clients, small business people, are just throwing their hands up, and I do not know what to tell them." That is just from a small business perspective, let alone all the other issues that are going to be arising here.

As I discussed earlier and as you well know, a lot of people have no idea about all of this. People just do not know a lot about it. The Kaiser poll pointed that out. I understand you have hired a contractor. I am just worried that that is going to be money down the drain, because contractors like to make money more than they like to do anything else. That is their job. They have to worry about their shareholders and whatnot.

Also, the other agencies are all involved. I think people are going to be really confused. You could maybe give some thought to one-stop shopping somehow, so you go to one location, a business person, to get the answers. I just would tell you, I just see a huge train wreck coming down. You and I have discussed this many times, and I do not see any results yet. What can you do to help all these people around the country wondering, "What in the world do I do? How do I know what to do?"

Secretary SEBELIUS. Mr. Chairman, as you know—and we have had these discussions a number of times—we certainly take outreach and education very, very seriously. It is one of the reasons that I think we were incredibly disappointed that our request for additional outreach and education resources was not made available in the CR of 2013.

Having said that, we have engaged in efforts with the Small Business Administration, which is doing regular meetings around the country with our regional personnel. We have just released a

Request for Proposal for on-the-ground navigators, individuals who come out of the faith community, out of the business community, out of the patient community, out of the hospital community, who will be available to answer questions, walk people through scenarios, hold seminars.

We do regular seminars and webinars, but we also understand that people have a lot of questions, and we are deploying as many resources as we can to answer those questions and get folks ready to engage in open enrollment on October 1st.

The CHAIRMAN. Well, do you have benchmarks? Do you have dates by which a certain number of people know what is going on? I mean, all these polls, for example, show that we are not making much headway. Do you have a goal that 2 months or 30 days from now, when that same poll is taken, that that percentage is down by X percent, in 60 days from now it is down by X percent, so people know where to go and what to do?

Are you surveying the professional accountants who work with businesses to get a certain percent who feel confident? I mean, you need data. Do you have any data? You have never given me any data, you just give me concepts, frankly. Government is not a business, but you are going to have to have some data benchmarks to figure out how much progress you are or are not making.

Secretary SEBELIUS. Well, we do not have benchmarks for how many people know what. We do not intend to do polling and testing in terms of what people know. We do have some very specific benchmarks around open enrollment, and we have a campaign and a plan to lead up to open enrollment.

The CHAIRMAN. And what is it, the campaign and the plan?

Secretary SEBELIUS. Well, Mr. Chairman, as we have discussed, there will be people on the ground starting this summer. There will be——

The CHAIRMAN. How many?

Secretary SEBELIUS. I cannot tell you at this point.

The CHAIRMAN. At what point in the summer? Geographically, what States? This is the kind of information I am asking for. You are only going to be able to do a decent job if you know the answers to these questions.

Secretary SEBELIUS. Yes, sir. And I would be happy to give you all of the specifics. As I said, we just put out the Request for Proposal. I cannot tell you about the numbers because we do not have the information back yet about how many people in which States are going to be actively engaged on the ground, but I will be happy to share that with you as we move forward.

The CHAIRMAN. And it depends upon States that have exchanges and those that do not. There are just a lot of factors here.

Secretary SEBELIUS. We will be focusing the Request for Proposal for navigators at this point on the States where the Federal marketplaces will be in place.

The CHAIRMAN. What is a navigator?

Secretary SEBELIUS. A navigator is going to be an individual who will go through training and be available to help educate individuals or groups of people——

The CHAIRMAN. How many Americans know what a navigator is?

Secretary SEBELIUS. Pardon me?

The CHAIRMAN. How many Americans do you think know what a navigator is?

Secretary SEBELIUS. I have no idea.

The CHAIRMAN. I will bet you it is about—well, we have 2 here. All right. You can understand my angst. I am going to keep on this until I feel a lot better about it. Thank you.

Next, Senator Nelson.

Senator NELSON. Thank you, Mr. Chairman. Madam Secretary, thank you for your public service.

Back when we passed the health care bill in this committee, I was kind of lonely in offering an amendment. There was great angst that was taken in the White House for my amendment, which was that the Federal Government, in paying for drugs for Medicaid recipients, when they became 65 years of age, they were suddenly eligible under Medicare for their drugs with the prescription drug bill.

But, lo and behold, the U.S. Government, the taxpayers of America, were not going to pay for the price of the drugs with the discounts or rebates that they paid when they were 64 years of age, but, when they turned 65, they got their drugs under Medicare, and we were paying premium prices for the same drugs, for dual-eligibles.

My amendment was defeated 10 to 13, and a very strong position was taken by the White House in opposition. The President has reversed course in this budget. It, when I offered the amendment, saved $117 billion over 10 years. Now it is $123 billion in savings in the President's budget, and CBO scores it and says it is something in excess of $140 billion. Why the change?

Secretary SEBELIUS. Well, Senator, I think that the wisdom of your original proposal has finally been seen. There is no question—again, you and I have both worked at the State level in prior lives. Having negotiated Medicaid rates as a Governor and then having that same individual, as you say, move into a premium class, did not make a lot of sense, particularly as we are looking to, not only save dollars in these very important public insurance programs, but save dollars for the individual who is, again, responsible for part of the drug benefit.

So I think this proposal captures what you were trying to do years ago and will save these important programs some significant dollars at the State and Federal level, which is all good news.

Senator NELSON. Well, you know the attacks against the President's proposal and the amendment 4 years ago. It is going to reduce research, it is going to limit access, it is going to result in higher consumer prices. How do you respond to those attacks?

Secretary SEBELIUS. Well, I think that we have a pretty good track record on Medicaid negotiated rates and the wide variety of drugs available to individuals in the Medicaid program. There is no question that the dual-eligible population, the approximately 9 million Americans who qualify for both Medicare and Medicaid, are often the most expensive population in any Medicaid program in any State in the country, so having a sensible, and I think proven, way to lower some costs around that population, while not slashing benefits, is a win-win situation.

Senator NELSON. Madam Secretary, we are losing a lot of money to Medicare fraud, Medicaid fraud as well, and we are going to be having a hearing on this in the Aging Committee. Can you give us some sense of, do you see that we are going to be making any progress, and what new activities are trying to stop this hemorrhaging of all the money?

It is so bad in Miami that people open up a store front, and there is no activity in the store front, and they start billing Medicaid. Of course, just recently there was this person down there who was billing, and ended up getting $50 million for mental health services. That is one way to save a lot of money.

Secretary SEBELIUS. Well, Senator, I could not agree more. I think that is one of the reasons the President's budget has asked for additional mandatory fraud resources, because we have a very good story to tell. This President asked the Attorney General and me to elevate the anti-fraud effort to a Cabinet-level position. We created a new joint task force. Unfortunately, in your State are some of the hot spots, I would say, in the country.

But we have implemented a variety of strategies: more on-the-ground strikes, more prosecutions, more money than ever before. In fact, we have doubled the amount returned to both the Medicare trust fund and Medicaid beneficiaries but, in addition, implemented re-credentialing for some of the known areas where providers were just entering the program and billing.

We have a much stricter standard to get in in the first place. We also have implemented predictive modeling, a computer-based system which tries to track the billing irregularities the same way a credit card company could go after someone who suddenly charged five flat screen TVs from Dubai to your credit card, and they can spot that and call you in advance and stop the payment going out the door. We finally have that capability within the Medicare system. It never existed before. So we are trying to approach this from multiple fronts.

I think the story is good, but there is a lot more we could do. Returning almost $8 for every $1 we spent last year I think is very good news, but clearly this is a huge program. Thousands of providers, millions of dollars go out the door every day. We take fraud and abuse incredibly seriously and want to use more resources to really beef up the efforts that have proven successful.

Senator NELSON. Mr. Chairman, in closing I would just say that all the new doctors we are going to need to implement the health care bill, we cannot keep cutting graduate medical education, which is a Medicare subsidy for residents. That has happened to my State, it has happened to your State, it has happened to Nevada. That is inadequate in the President's budget.

Thank you, Mr. Chairman.

Senator HATCH [presiding]. Well, thank you, Senator Nelson.

Senator Roberts, you are next.

Senator ISAKSON. Mr. Chairman? Mr. Chairman? Down this way.

Senator HATCH. Yes?

Senator ISAKSON. Could I be so rude as to interject for 1 second? Last week I accommodated Senator Roberts and let him take one question out of my time so he could go to a meeting. I have to leave too, but I have one relevant point for Ms. Sebelius with regard to

Chairman Baucus's question on the navigators. So, if Mr. Roberts would yield for just one second?

Senator ROBERTS. I would be more than happy to yield to my distinguished colleague. It's "Se-bee-lius," by the way, not "Se-bay-lius." He was the composer, she is the Secretary. [Laughter.]

Secretary SEBELIUS. From my Senator.

Senator ISAKSON. I stand corrected.

Senator HATCH. Both are good at composition, is all I can say.

Senator ISAKSON. Right. Madam Secretary, Senator Baucus asked you the question about these navigators.

Secretary SEBELIUS. Yes, sir.

Senator ISAKSON. I understand you are about to award $54 million in contracts to hire navigators in the States with exchanges. Is that correct?

Secretary SEBELIUS. That is correct, sir.

Senator ISAKSON. Yet, CMS's rule on medical loss ratio is putting most agents and insurance brokers in the business of selling health insurance out of business because of the 85-percent threshold for the medical loss ratio.

So we are spending $54 million to hire navigators, yet, because of the rule on the medical loss ratio, we are cutting out most of the people who provide these services in the private sector, which costs the government nothing.

I have legislation with Ms. Landreiu and some others to amend that, because I think we need to revisit that medical loss ratio rule and see what effect it actually has on people getting credible information from people who make a living doing it, and have for years.

Secretary SEBELIUS. Well, Senator, I would be happy to take a look at the legislation. There is no prohibition, first of all, for agents and brokers to be navigators. Second, exchanges at the State level can designate agents and brokers as part of the funding stream to do the outreach, but we certainly have not eliminated their ability to do their jobs and to actually bring people into insurance companies as they have for a long time.

The medical loss ratio, as you mentioned, deals with what is characterized as medical costs versus what is characterized as overhead costs. You are correct that the rule does not include an agent and broker's salary or commission as part of what is characterized as a medical cost.

Senator ISAKSON. I appreciate your looking at it, because, as it is applied, what it basically does is preclude those people from being compensated by the way the ratio applies. That is the reason that we think it ought to be——

Secretary SEBELIUS. Well, they could easily be in the 20 percent of overhead. They just cannot be counted in the—it is basically 80/20, but they cannot be counted in the 80 percent that has to go to medical costs.

Senator ISAKSON. Thank you very much.

Thank you, Senator Roberts. I appreciate it.

Senator HATCH. Senator Roberts? Re-start the time for him.

Senator ROBERTS. I thank the Senator for his contribution and his question. I know the Secretary will be taking a hard look at that. And she was an insurance commissioner for our State of Kan-

sas prior to becoming Governor, so she certainly has that background.

Madam Secretary, we have 83 hospitals, as I think you know, that are designated critical access hospitals. In the budget on page 53, I noticed that we are going to take a whack—another Lizzie Borden whack—at the critical access hospitals' Medicare reimbursement rate, and there is a mileage requirement. We are back to that.

I can remember years ago when we had somebody from—at that point it was Health, Education, and Welfare—indicating it was 100 miles, but it was all right to not include Goodland because they had 4-wheel drive. I could never figure that out. So, I hope we do not go back to that. I wish you would take a look at the critical access situation. The chairman of the committee has a lot of feeling about that in Montana, and I know in a lot of other rural areas, so, if you could take a look at that, I would appreciate it.

Then, on page 56 of the budget, there is a line here in regards to IPAB. Well, my opinions about IPAB are well-known. I think we would probably be at odds with that, but I think they will ration patient care. They are going to set the Medicare reimbursement according to a formula here. I will not read the whole thing. It is a growth rate to meet the target, and they are going to save $4.1 billion. So we have $1.4 billion out of the critical access hospitals, $4.1 billion in regards to IPAB. They are not even set up yet.

I just do not understand. They have not been set up, and we have no idea how the recommendations are going to be implemented, yet we are going to expand and strengthen them. I wish you would take a look at that and see if you could get back to us. I apologize for handing three questions to you, but, because of the time limit, I wanted to cover these three.

About 53 people—we think 53 people—have died, and over 700 people have become ill as a result of the meningitis crisis. I am talking obviously about pharmacy compounding. The FDA has put forth a legislative proposal which has been detailed on the Commissioner's blog, and she has stated: "Funding will be necessary to support the inspections and other oversight activities outlined in this framework, which could include registration or fees."

I am working on legislation, and so are the members of the committee, that would hopefully be of help here, both to guarantee the efficacy of the program and then access to compounding. It is not mentioned in the President's budget. I have looked, and we cannot get a cost estimate.

If you could provide that, with regards to the legislative proposal put together by the Commissioner of FDA, I would greatly appreciate it. If you could comment on that or anything else that I have brought up, you have about 2 minutes.

Secretary SEBELIUS. Well, I would be happy to, Senator. First of all, I will try to get a specific cost estimate for the very important legislation I think that you and your colleagues are working on with the Food and Drug Administration, which I think would give some additional authorities over the non-traditional compounding and make sure that traditional compounding can move forward.

I do not think that the FDA has a legislative proposal that is specific. They have been working around some principles with the

HELP Committee, so that may be part of the confusion. They do not have a draft piece of legislation. I think they have been providing technical assistance to the HELP Committee, but I will see where we are on a dollar recommendation.

With IPAB, the President has recently sent to the leadership of the House and Senate, majority and minority, a request for recommendations for potential candidates. The legislation contemplates the President making appointments, but in consultation with the House and the Senate, so those letters have been received by leadership.

The President's budget does suggest that the Independent Payment Advisory Board would not kick in unless Medicare spending exceeded the inflation by more than 0.5 perent, CPI plus 0.5 perent. We do not anticipate, according to the latest CBO initiatives, that that would hit until about 2019 on the track that we are on.

So we are in the process of consulting with leadership around potential members, but, as you know, those members would have to be confirmed by the Senate, so there will be multiple steps and opportunities for consultation before that board would ever occur.

Finally, I share your concern about the incredible importance of critical access hospitals, particularly in rural communities, and we will certainly take a look at the specifics in the budget and be back in touch.

Senator ROBERTS. I appreciate that. Thank you.

Secretary SEBELIUS. Certainly.

Senator HATCH. Thank you, Senator.

Senator Casey?

Senator CASEY. Thank you.

Madam Secretary, thank you for being here today and for your great public service. This is hard work that you are doing, especially with regard to health care, in addition to the other responsibilities you have. I appreciate the time we spent prior to the hearing.

I wanted to ask you about children. But, as a preface to that, I wanted to note in the budget a couple of highlights, some of which you have already referred to, but the parts of the budget that focus specifically on children bear mentioning.

The home visiting program, as well as Early Head Start and the Child Care Partnerships, both of which you have set forth on page 4, the Child Care Quality Fund, child support, and fatherhood initiatives, all of those are so important, and I want to commend you and the Department for that. I know that for NIH, the proposed increase is $471 million. That is commendable and necessary, despite all of the challenges we have. If we are not investing there, we are making a big mistake.

But I wanted to focus on maybe two questions, really, on children. First, with regard to the Children's Hospital graduate medical education program, I am told that we have three great examples in Pennsylvania: two in Philly, one in Pittsburgh—with Children's in both cities, and then St. Christopher's in Philly. But I am told that these hospitals comprise less than 1 percent of all hospitals, yet train nearly half—the number, I guess, is 49 percent—of all pediatricians.

This is a budget allocation which has been in the 6-figure millions. The proposal in the budget is just $88 million in funding for that program. I think that is a mistake. I do not agree with it. I do not know how we are going to get the trained pediatricians that we need and I think the Affordable Care Act contemplates, if we do not have that investment. If you could give us the rationale for that $88 million.

Secretary SEBELIUS. Well, Senator, first of all, I do not disagree at all that the children's hospitals provide not only incredibly important service and health care for children, but also training opportunities for pediatricians, so they are sort of doing double duty.

What the President's budget reflects is graduate medical education direct costs. What is eliminated from the budget recommendation is the overhead and administrative costs. We feel that this is sufficient to provide the number of residency slots.

Often children's hospitals operate, frankly, at a more significant margin than other hospitals do, and it is not a choice we would have made in better budget times, but providing the direct costs for the number of residency slots that are currently in hospitals is one way to make sure that we train the pediatricians of the future.

Senator CASEY. Well, I hope we can spend some time on this, because, when you have that small of a percentage of hospitals providing that level of training, I think we should go back to work on that so we can get back to you and spend some time on that.

I also wanted to ask—and I raised a similar question or two with regard to Marilyn Tavenner's confirmation hearing—how children will fare in the new world of the exchanges and how you see the Department's role in monitoring the impact on children with regard to the exchanges and making sure that, if a child would, under a different set of circumstances, get a particular level of care, that they are going to still be able to get that same kind of care and treatment under the exchanges.

Secretary SEBELIUS. Well, I think it is a great question, Senator. The CHIP program, which does offer, I would say, enhanced benefits for children, as you know, continues to exist. One of the benefits for children that is sort of an indirect benefit, but I think can be very real, is that there is a lot of evidence that indicates that, if parents have insurance, children are more likely to go to the doctor on a regular basis.

If the family does not have a health home, in spite of the fact that a child may have access to services, if the family really does not have family coverage, then the likelihood of actually accessing those services is significantly diminished. So I would say there are some value-added benefits around family coverage that do not exist right now that will be the case in the future.

While the exchange programs will not have a specific mandated package of benefits for children, what I think does exist in the commercial market right now, particularly in the employer market which is being modeled as the benchmark plan, is a pretty robust set of services and supports around children's health, and it is there because of employee demand.

So we will watch that very closely, and we would be delighted to continue to work with you and your office. I know looking out for American's children is certainly one of the areas that you have

taken a great leadership role on, and we would be happy to work with you as these plans are being implemented.

Senator CASEY. I appreciate that. I hope, as some of the benefits from medical homes play out for families, that that will have a positive impact on kids, especially children with chronic and complex medical conditions.

Secretary SEBELIUS. Well, certainly the medical home model, I think, and coordinated care models, both offer some enhanced benefits for children who have, as you say, chronic or multiple conditions. Right now, too often that care is segmented into a variety of specialists who do not talk to one another, who may not coordinate with the family, so I think testing some of those models around chronic conditions—while people often think of that as an older Americans issue, I think there are cases where certainly it will be of enormous benefit to some of our youngest patients.

Senator CASEY. Thanks very much.

Senator HATCH. Senator Cardin?

Senator CARDIN. Thank you, Mr. Chairman.

Madam Secretary, thank you for your extraordinary service during a very difficult time. I want to bring up a couple of subjects in regards to the implementation of the Affordable Care Act and how the budget submitted by the President would advance those goals. Shortly after the passage of the Act, you and I had a chance to talk about the commitment we made to minority health and health disparities, the elevation of the Institute at NIH and the offices in all the relevant agencies, including HHS.

You made a commitment then to adequately fund those initiatives, and I thank you for following up on those commitments. There is some concern today as to whether there is adequate budget support to implement the type of grant-making in the offices, including your Office of Minority Health, and whether the Institute at NIH has adequate resources in order to make the type of progress that we would like to see made as a matter of what is right policy for this country, as well as smart policies that reduce health care costs.

Can you just give me an update as to how your strategy is being implemented to fund this commitment?

Secretary SEBELIUS. Yes, Senator. I think that there is no question that we have taken very seriously the charge to not only track health disparities, but reduce health disparities. The passage of the Affordable Care Act and the full implementation of the Affordable Care Act, I think, will advance that cause, probably faster than any other single thing that we could possibly do to close the gap in health coverage.

Having said that, while the budget, I think, in some of the offices within the Secretary's office may have a reduction of some grant funds, the overall budget has a significant increase in funding for minority health issues, and that is one issue that we take very seriously. I think there are an additional couple hundred million dollars that are both in the Health Resources and Services Administration and some funding within the NIH.

Unfortunately, NIH funding does not increase as significantly as we would like, and they also lost $1.5 billion through the sequester cuts. So we are in a more restrained situation I think than we

would be otherwise, with not only a tight budget moving forward, but also a fairly significant cut in their grant-making authority that hit in 2013.

Senator CARDIN. Thank you. I understand the challenge of sequestration, and I would just urge us to be as strategic as we can to make sure that mission moves forward.

Secretary SEBELIUS. Yes.

Senator CARDIN. I am going to make a request of you to personally take a look at a regulation that has been issued as it relates to pediatric dental care. Ms. Tavenner was before this committee, and I questioned her and then submitted questions for the record.

As you are probably aware, you are in the process of implementing a regulation that would allow for stand-alone pediatric dental policies to have separate deductibles, with no assurance that in fact individuals will have that coverage. I believe both of those actions by HHS are contrary, clearly to the intent of Congress, but I think also contrary to the legal ability to issue such regulations.

We intended that pediatric dental care be an essential benefit. "Essential benefit" means people have affordable coverage. A $700 deductible per child is not a quality plan, it is 2nd-class coverage. Most families will not reach $700 a year in pediatric dental care. Why would they then buy insurance, particularly if it is not going to be required? That to me is contrary to what Congress intended, and I believe it is contrary to law.

So I would just ask if you would personally review this regulation and the legal basis of this regulation and make an independent judgment as Secretary as to whether you believe this is the right policy and the right legal path for us to take as it relates to pediatric dental care.

Secretary SEBELIUS. Senator, I will commit to do that. I know that concerns have been raised about what is a proposed regulation. The comment period is still very much open, and so this is not a settled formula going forward. But I hear your concerns. We have heard them from a number of people, and I will commit to taking a personal look at exactly what the impact would be on the very families we want to serve.

Senator CARDIN. Thank you. I appreciate that, Madam Secretary.

Secretary SEBELIUS. Sure.

The CHAIRMAN. Senator Thune?

Senator THUNE. Thank you, Mr. Chairman.

Madam Secretary, welcome back to the committee. Thank you for being here.

I have worked with several of my colleagues on this committee on a white paper which we issued yesterday, and it outlines concerns we have about the electronic health record program that was created by the stimulus bill.

One of the chief concerns is that the program was not thoughtfully planned and that CMS and the Office of the National Coordinator for Health IT are insufficiently focused on the issue of interoperability.

I am also concerned that the Office of the National Coordinator has a philosophy that is focused on simply pushing Federal taxpayer dollars out the door and using the dollars out the door as a

measure of success of the program without sufficient oversight of those payments. I am wondering if you agree with that.

Secretary SEBELIUS. I do not.

Senator THUNE. Well, it is noted in our report that providers simply self-report that they have met the necessary criteria to receive Federal incentive payments for adoption of health IT with no documentary evidence necessary.

Your agency's Office of the Inspector General has warned that this is a potential problem. The Inspector General issued a report last year saying that Medicare "does not verify the accuracy" of the self-reported information by health providers claiming the incentives prior to the payment, and even noted a few examples of providers who had reported themselves eligible but had not actually met the requirements.

So my next question is, do you agree that self-attestation is a problem in terms of them certifying themselves eligible?

Secretary SEBELIUS. Well, Senator, we take the adoption of electronic health records very seriously. I cannot imagine any other industry which represents close to 17 percent of our GDP which is trading information on paper files.

So this is a significant move forward. We have about one-third of the individual providers online, with another third in the queue, and almost two-thirds of the hospitals are now in the process of adoption.

I think what has to be attested to—my understanding is—will be able to be tested more thoroughly when the interoperability standards go live in 2014, as you know, in Meaningful Use Stage 2. That is not yet up and running. There is a lot of concern.

It is sort of the gold standard of electronic health records. If they cannot talk to each other, it is really not a venture that takes us very far. We understand that. But it is not live and running, and it has been the focus of both the Policy Committee and the Production Committee from Day 1.

Senator THUNE. Well, in responses to questions from this committee, Ms. Tavenner, the nominee to head CMS, stated in written comments that there will now be a delay in implementation of Stage 3. I asked the question. But given that it seems clear that the leap to interoperability is not possible from the already existing requirements for Stage 2 to Stage 3, what are your plans for Stage 3 that ensure taxpayer dollars are being wisely used to invest in interoperability?

Secretary SEBELIUS. Well, again, we have not gotten to implementation of Stage 2 yet, so you may be reading the final chapter before we launch it.

Senator THUNE. Right.

Secretary SEBELIUS. January of 2014 is when the portion of Stage 2 that deals with meaningful use will be up and running, and I think we have full plans and a timetable to then move to Stage 3. But we do not right now have a plan about what could or could not happen, because we need to fully implement Stage 2.

Senator THUNE. But are the rules for Stage 2 not final?

Secretary SEBELIUS. The rule is final? Yes. Yes.

Senator THUNE. All right. Well, in terms of——

Secretary SEBELIUS. But it is not up and running yet. The timetable has not been reached.

Senator THUNE. The thing I guess I would say I am concerned about is, the leap from the current Stage 2 requirements, particularly with regard to interoperability, is going to be very difficult in terms of the challenge that is going to be faced by a lot of rural providers. So my next question is, what are you doing to ensure that small rural providers' needs are being considered in terms of Stage 2, and then ultimately Stage 3?

Secretary SEBELIUS. Well, Senator, part of the framework of this implementation was really to create information and technology exchanges in every part of the country. They are focusing most specifically on critical access hospitals and on small providers, knowing that the luxury to have a big IT department or have people who could implement this in a significant period of time was not there.

So in every State there are individuals who are sort of the—I compare them to the farm extension services, folks who are on the ground who literally come office to office, hospital to hospital, spend time on how to convert what the best strategies are, how to be engaged and involved.

We have found, at least in a State like Kansas, which shares the challenges I think that you see in your State, that that strategy has been enormously effective, and small providers are engaged and enrolled with those extension operations and find them to be kind of their service team on the ground.

Senator THUNE. Well, the only thing I would say is, I hope that, as we move forward with this, that the focus really will be on the issue of interoperability.

Secretary SEBELIUS. You bet.

Senator THUNE. Because we have asked questions numerous times at the committee here of folks who have testified in front of the committee about what is happening with regard to interoperability. It may be that a lot of providers are creating their own health electronic records, but the idea that somehow they are going to be able to communicate with others just seems to be nonexistent in many cases.

So, you have these silos out there, but until they can talk to each other, we have not solved this problem. And that is why I say, a lot of the money that has gone out the door, that seems to be the metric instead of, what is the metric or what is the measuring stick for whether or not we are succeeding in the issue of interoperability?

Secretary SEBELIUS. Well, I would say, again, Senator, from the outset—and I would certainly agree with you that that has to be the north star of whether electronic records work—it is not whether paper files are in somebody's computer, but it is whether or not you can measure, share information, not only across a State, but across the country and conceivably across the globe.

So that has been part of the framework of the formula to look at what sort of IT systems would qualify, what the specs have to be. It is part of what has to be attested to, that a conversion to an electronic record system has to have the capacity to actually get to Stage 3 along the way and demonstrate that. It does not have to

be part of the operating system from Day 1, but it has to have the capacity to add that on.

There are very specific kind of specs as a part of what qualifies for the incentive payments, so I think that has been part of what the technical committee that has been the advisor to the Office of the National Coordinator from the beginning has been focused on: how, at the end of the day, you make sure that these systems actually work.

We were strongly advised, Senator—and it came at the dismay of, I would say, some of the biggest IT companies—but we were strongly advised not to choose one system, not to have one winner in this market and everybody else a loser, but rather to focus on a series of specs that would, at the end of the day, make sure that these systems were interoperable but then would allow providers, hospitals, and others to either make conversions to the systems that they had or purchase any variety of new equipment. That has really been the framework, to have it be more open-source, but certainly with interoperability at the end of the day.

Senator THUNE. I am glad to hear that you are focused on these specs. I do not know that these specs exist. Again, the self-attestation model that is being used seems to lack the kind of documentary evidence that the folks who are eligible for some of the assistance that is coming with this are actually focused on, these right metrics that you are talking about.

So I guess the only thing I would say in conclusion is that we look forward to engaging with you and your department on this, and we are going to continue to solicit feedback from stakeholders about where they are. I think this report that we put out will maybe put a fine point and additional focus on that. So, thank you.

Secretary SEBELIUS. Thank you.

Senator CANTWELL [presiding]. Thank you, Senator Thune.

Madam Secretary, welcome. Thank you for being here. Thank you for your help on the basic health plan. I appreciate that very much. I also thank you for the President's budget as it relates to $1 billion for mental health programs for substance abuse and mental health services and $460 million for the mental health block grant services. I think that will go a long way to helping States deal with these issues, so I very much appreciate that.

I wanted to follow up on my colleague from Pennsylvania's question, particularly as it related to graduate medical education. This is a big issue for all of us in the country, obviously, with the shortage that we are looking at, something like 90,000 specialists and primary care physicians by 2020.

For us in the WWAMI region—Washington, Wyoming, Alaska, Montana, and Idaho—we are even below the national average now, so that is why we care so much about this issue.

When it comes to figuring out the impact, he mentioned Children's Hospital, which I could say probably the same about Seattle's Children's Hospital. But the issue is also trauma centers or burn centers like Harbor View Hospital. So, when you look at this reduction in indirect medical education, it impacts that workforce. They have residents there whom they are not reimbursed for under the Medicare model.

So how do we look at this issue when there is specialized training that goes on at these trauma centers, and they want to get their graduate medical education? How do we look at this and make sure that these facilities can keep running and operating during this time period?

Secretary SEBELIUS. Well, again, Senator, I think certainly the training of new doctors is of critical importance. We know what an important role graduate medical education funding through Medicare plays in that training, which is why I would say, even in these very difficult budget times, there was an attempt to make sure that we were funding the direct costs, as well as doing some additional looking at where there were real gaps in services.

A lot of the workforce analysis looking forward indicates that it is in primary care providers, gerontologists, others where we often have significant gaps. So we have not only tried to have a budget that supports the direct cost of graduate training, but also shifts some of the unused GME slots from areas that may have been more focused on specialty care into areas specializing in primary care, pediatric care, gerontology care, hoping that the effort to address people's preventive care needs at the front end will be met by a health care provider.

So we would be interested in working with you and hearing from you about the impact of this on a critical center like the burn center and the trauma centers that you have in your area.

Senator CANTWELL. Thank you. We will get you some information on that.

Secretary SEBELIUS. Sure.

Senator CANTWELL. I do not know that that is the intended consequence, but I think people are concerned that that will be the unintended consequence, because those costs are not covered.

Secretary SEBELIUS. You bet.

Senator CANTWELL. So maybe there is something we can do there.

If you could comment, too—at the University of Washington, we train so many primary care physicians. I think we are number-one in the Nation. But we are also very high on the list, in the top five, of institutions with NIH funding. So this NIH budget issue is a very big issue. We understand what you have done.

Obviously, for these institutions we are hoping to get closer to $32 billion than $31.5 billion. And you think, that is close, what is the difference? Why does that matter? Well, for us, the total economic impact for research is 8,800 jobs and $470 million in wages, so this will be a big impact to us. In fact, one of our professors was quoted in the *Wall Street Journal* as saying, "People are asking me whether they should leave science."

So, given what is already in the budget, what is being discussed as far as sequestration, are we having a chilling effect on this investment in science? What can we do to help mitigate the sequestration's impact on NIH funding?

Secretary SEBELIUS. Well, I think that the President has proposed a budget going forward and a way to have a sustained and balanced approach to both reducing the deficit, but making some of the critical investments that we need to make. Actually, the budget anticipates removing sequestration.

Senator CANTWELL. I should just add—sorry to interrupt—we are all cheers about the magnificent contribution for brain research. Thank you.

Secretary SEBELIUS. Well, I think that is an example of the President's belief that we cannot cut our way to prosperity in the future, that we must invest. Certainly scientific research is one of the most critical investments to keep the innovation and research at the front end.

So he very much supports outlining the mapping strategy, which could have a huge impact not only on cures of the future, but when you think about health costs related to everything from autism to Alzheimer's. If we want to really get our arms around what is happening to health costs in the future, this kind of brain mapping has an enormous impact.

As you say, I think Dr. Collins estimates that there is about a 7:1 return, that every dollar in research grants generates about $7 in economic activity in the community where those research grants end up, in terms of jobs and scientists. So this is clearly a win-win investment that the President very strongly believes in and supports.

Senator CANTWELL. Well I hope, as we continue to talk about and see the impacts of sequestration, the administration will speak out on this, because it is a very short-sighted approach, particularly when it comes to the NIH budget.

I hope that we can get organizations and institutions, whether it is the Institute of Medicine or others, to put pencil to paper and really measure this, as you just did with that 7:1 ratio. We may be saving a few dollars now, but it will cost us millions, if not billions, more if we do not continue the investment in research. So, I hope we can make that point to our colleagues here. Thank you.

I think, Senator Portman, you are next.

Senator PORTMAN. Thank you, Senator Cantwell. I think I am last and only, as well as next. [Laughter.]

Senator CANTWELL. You never know who might come back.

Senator PORTMAN. Exactly. Well, thanks very much.

Madam Secretary, thank you for being here. We just had an interesting exchange about the need for us to do more research. I would just make the obvious point that that part of our budget is being squeezed more and more and more by the reality that the mandatory spending part of the budget—which is now 65 percent of the budget, which is the part that is on auto-pilot, that is not appropriated every year—is the fastest-growing and now obviously biggest part of the budget and one reason the research dollars are tough to find, and one reason children's hospitals are concerned as they see the squeeze, including our great Children's Hospital in Cincinnati. On the mandatory side of the budget, of course, the number-one cost driver is health care, by far.

The Congressional Budget Office, which is a nonpartisan group here in Congress, has just given us another report. This one is looking forward to the next 10 years, what is going to happen in terms of our budgets. They say there will be a 110-percent increase over the next decade, from $800 billion to about $1.65 trillion—a 110-percent increase in health spending on the mandatory side.

They also make the point that if we do not address this problem, obviously it continues to grow. Then, over the next 3 decades, they say that the health spending in essence bankrupts the country, because you cannot raise income taxes, at least not high enough, to catch that level of spending. It just cannot be done.

I think it is indisputable that that is our number-one problem in terms of the budget. Since we are here today talking about the budget, I just wanted to get your thoughts on that.

The White House has proposals in the budget that, as I read it, would reduce that growth from about 110 percent over the next 10 years to about 100 percent, but it is actually 104 percent because it also assumes a permanent Medicare doctor fix, and that estimate also does not include the $90 billion in the canceled sequestration cuts to Medicare which would further decrease health savings. So it is somewhat more than a 104-percent increase in spending rather than 110 percent. No structural reforms.

The question is, with the trustees having told us the Medicare trust fund is insolvent in 2024, and again, with everyone who has looked at this saying our number-one driver in all this is Medicare, and once again the Medicare funding trigger having been ignored—so no proposal from the administration, even though it is required by law—my question is, what do you suggest in terms of dealing with this problem which everyone now acknowledges? How are we going to close these tens of trillions of dollars in unfunded liabilities that the trustees have estimated? Where is the administration's plan to bring long-term solvency to our Medicare program?

Secretary SEBELIUS. Well, Senator, I think that there is no question the President is eager to work with Congress to have a long-term strategy that both ensures that we keep the commitments that we made to seniors and others in the mid-1960s around benefits in their senior years, as well as looking at the viability of funding and support for Medicare and Medicaid into the future.

I think, in the last 3 years, there is an enormously positive story to tell, a very different story than we have seen really over the history of the Medicare program. Last year alone the per-beneficiary cost rose at the smallest level that it has ever done in history. It is a four-tenths of 1 percent increase per beneficiary.

As you know, part of the growth right now deals with demographics, not health costs. I think that effort is very much under way to really re-think and re-look at how we pay for health care, shifting from a volume payment to a value payment, testing models for the first time ever that could lead to significantly better care at lower cost. Those efforts are very much under way.

Medicaid spending is down 2 percent from 2011 to 2012, again, a decrease in year-over-year spending. Again, that has not been seen before. So I think, structurally, the CBO has revised its estimates recently based on that cost trend. We know that the Affordable Care Act added about 8 years to the life of the trust fund.

The budget on the table adds another 4 years. But if this cost trend continues, I am optimistic that we can revise that even further. We would be eager to look at a longer-term strategy around how we make sure that the commitments to seniors and the most disabled Americans are fulfilled and not shifting the costs onto

them by destroying Medicare as we know it, but also looking at the longer-term funding challenges.

Senator PORTMAN. Well, with all due respect, no one is talking about destroying Medicare as we know it. People are looking at sensible ways to reform the program so it is strong and can be there in future generations. And by the way, the Congressional Budget Office's report is from a few weeks ago, so it does include that data. Your own data indicates the same thing, which is, these costs are unsustainable by any measure. So I hope you will look at some reform that is more structural.

I know that you support in the budget some means-testing, for instance, but I would ask you also to look at Medicare Part D. Marilyn Tavenner, whom you know is your nominee for CMS, came before this committee and told us the actual costs for Part D are 40 percent less than the original estimates. CBO has now reduced its 10-year cost projections by over $100 billion in each of the last 3 years.

Your Deputy Administrator has said that Part D costs have remained flat for years and are expected to decline in 2014. You have also reported that, over the past 3 years, the average monthly benefit premium has stayed essentially flat, right at about 30 bucks a month.

So I believe this indicates that there is something going on in Part D, which is frankly that the private sector has to compete for the business of tens of millions of seniors. That is one reason that those costs have been less than projected.

So I encourage you to learn from and not undermine Part D. I notice in your budget you target Part D again, particularly the Medicare Advantage programs, which as you know, given your Ohio roots, is critically important in our State: over a third of seniors enjoy it. So I would just ask for you to take a look at that Part D success rate. In my view, I think that is where some of the structural reforms can and should be made. I thank you for your time today and for your service.

Secretary SEBELIUS. Thank you, Senator.

The CHAIRMAN. Thank you, Senator.

Senator Menendez?

Senator MENENDEZ. Thank you, Mr. Chairman.

Madam Secretary, thank you for coming. There is a lot to applaud in the budget, certainly the $100-million investment to advance research education and outreach for Alzheimer's Disease, something that took my mother's life; the funding for community health centers is incredibly important; the quality primary care in communities throughout the Nation. Those are all great things.

There are still tough decisions to make, and savings to be had. I think we did a lot of that in the Affordable Care Act. I have long held that real long-term savings can and should be found by encouraging the efficient delivery of health care through measures such as increasing the use of electronic medical records—we are on our way there—promoting the efficient and well-managed delivery of medication, and improving coordination between acute and post-acute providers to ensure the appropriate care setting. Do you share those views as they relate to how we save money in those areas?

Secretary SEBELIUS. Yes, Senator. I think all of those are an enormously important shift in the way health care is delivered as opposed to just paying for volume, really looking at value proposals.

Senator MENENDEZ. Yes. So, with that having been said, I am a little dismayed at some of the so-called savings that are identified in the Medicare program that, in my mind, are nothing more than another set of cuts.

I look at that, and I say to myself—following on on Senator Portman's question as it relates to Part D—is it not true that the Part D program currently costs about 40 percent less than the original estimates and that the CBO has reduced cost projections by more than $100 million a year for each of the last 3 years?

Secretary SEBELIUS. Yes, sir, that is accurate. I think that some of the negotiating authority that you actually directed to CMS as part of the Affordable Care Act had a beneficial effect on some of those Part D negotiated——

Senator MENENDEZ. Is it not further true that under the Affordable Care Act, that with the donut-hole rebates and other cost-containment provisions, that beneficiaries have not only saved about $6 billion in drug costs since the law was signed, but that their premiums have been essentially flat?

Secretary SEBELIUS. Yes, sir.

Senator MENENDEZ. And so, given that the program is proving to be successful in providing seniors access to the drugs they need at costs that continue to be below estimates, could you ensure that the imposition of Medicaid-style rebates in the Part D program will not ultimately lead to restricted formularies, increased premiums, and higher out-of-pocket costs for beneficiaries?

Secretary SEBELIUS. Well, Senator, we are confident that the kind of drug strategies that provide available drugs for dual-eligibles are similar to what can be in place for those same individuals, as Senator Nelson said, when they are 64, and it should not change when they are 65. So we are confident that this will not only be a savings to the government, but actually make sure that beneficiaries have access to the critical drugs they need.

Senator MENENDEZ. So you do not believe that such a move will create restricted formularies?

Secretary SEBELIUS. No, sir.

Senator MENENDEZ. You do not believe that it will create increased premiums?

Secretary SEBELIUS. I think that there is no question that there may be some formularies that are in place, but, as you know, a dual-eligible does not lose any of his or her Medicare benefits, so they must have the same benefit package going forward.

Senator MENENDEZ. So how do we ensure that the research and development that makes us the leader in the world and that makes us globally competitive, and, maybe even more important than that, creates life-saving, life-enhancing drugs, does not get diminished?

Secretary SEBELIUS. Well, I share those concerns, Senator, but I feel that Medicare Part D, in spite of the fact that it has come in under the original estimates when the benefit was first created, is still paying at a much more substantial rate than the Veterans Ad-

ministration, than Medicaid programs, than a variety of other programs, so we are still paying premium dollars for a number of those drugs.

For these 9 million individuals, the budget assumes that, on balance, this is an appropriate way to both save some dollars going forward, but also make sure that those beneficiaries receive the critical medications that they need.

Senator MENENDEZ. I just do not think we will have the research and development dollars. If I may have another minute, Mr. Chairman?

The CHAIRMAN. Sure.

Senator MENENDEZ. With reference to hospitals, one question I had raised with you is, the imputed floor issue at CMS is pending. It is something that was part of the Affordable Care Act. It is a critical issue to New Jersey hospitals, and we are awaiting a response. I just want to bring it up again, because it is probably life or death for a whole host of New Jersey hospitals.

In line with hospitals—the Medicare cuts to hospitals—the President's budget calls for about $11 billion in cuts to graduate medical education and a $177-million cut for children's graduate medical education programs. Both of these are critical to train the next generation of doctors.

One of the things we heard about as we were in this committee debating the Affordable Care Act, which I was proud to support, is, how do we have the health care workforce to deal with millions more whom we obviously aspire to cover, looking at the age of many doctors, particularly in certain parts of our country?

So how is cutting back on the programs specifically designed to train new physicians going to provide for the needed increase in the workforce that we recognize we need?

Secretary SEBELIUS. Well, Senator, I understand the concerns about the reduction in graduate medical education. The budget is based on a design that would provide to hospitals and children's hospitals the direct cost for those residency training programs. It does not provide the overhead and administrative costs.

We feel that having the direct costs continuing to be paid should not diminish the number of residents who can be trained in those programs, but, again, it would not be a budget choice in a different budget time. It is a time of very scarce resources, and we are trying to make sure that we can fulfill all of our obligations.

Senator MENENDEZ. Well, I appreciate that.

Mr. Chairman, this is a concern. At the end of the day, after all the effort we exerted to provide coverage that was affordable—which was a big goal of the committee, to make sure we tried to control costs and at the same time amplify the universe of which Americans would be further covered who presently are not and stop having people going to the emergency room—it creates the necessity for a cadre of physicians in our country, and cutting in this particular field, while I understand the challenges and the tradeoffs, is just undermining the very essence of some of the goals that we intended under the Affordable Care Act. So, I hope we will be able to visit it as we move forward in our deliberations in the days ahead.

Thank you, Madam Secretary.

Secretary SEBELIUS. Thank you, Senator.

The CHAIRMAN. Thank you, Senator.

Madam Secretary, I know you are busy. I would just like to ask a bit more about the concept of 1-stop shopping, one resource center, someplace for businesses to go to so they do not have to deal with so many different agencies with respect to the implementation of the Affordable Care Act. Does that make any sense?

Secretary SEBELIUS. Well, Senator, there will be a 1-stop shop with the Shop Exchange up and running in January 2014, so business owners will be able to enter the marketplace through a 1-stop area, get the information about what is available, have a choice of plans. If the business owner qualifies for the employer tax credit based on the number of employees and the wages of those employees, that will automatically be part of the program.

So there will be a 1-stop shop available to small business owners who, as you know right now, often pay 18 to 20 percent more in the market than their large competitors, and we are very confident that they will have better choices, better prices, with the new marketplace that will be up and running.

The CHAIRMAN. The real concern here is from the business perspective more than consumers, individuals. I think I heard you say that the shop—I have forgotten what it is exactly called—will be delayed.

Secretary SEBELIUS. No, sir. That is not accurate. The shop will be up and running in every market in the country. For the States where the Federal Government will be operating the marketplace, we are delaying one portion of the shop plan, which is that employers, if they choose to do so, could offer a wide variety of plans to their employees.

Year 1 for the Federal marketplaces, employers will have a choice of coverage for their employees, but that choice will then be passed along. Year 2 and beyond for the Federal marketplaces, the employer, if he or she chooses, can then turn to the employees and say, you can choose among 15 different plans.

For State-based marketplaces, that employee choice could be available from Day 1. But we will have two steps. So, in 2014, all employers will have a choice. They will have a choice of plans to offer their employees. They just will not be able to say to that employee, should they choose to do so, you can choose any plan in the shop market.

The CHAIRMAN. All right. Well, as I said, I will be watching it.

Secretary SEBELIUS. Yes, sir.

The CHAIRMAN. We will be doing all we can. Let us know what help you need too. It is a 2-way street.

Secretary SEBELIUS. I will be happy to do that.

The CHAIRMAN. All right.

Secretary SEBELIUS. Yes, sir.

The CHAIRMAN. Thank you.

Secretary SEBELIUS. Yes.

The CHAIRMAN. Good luck.

Secretary SEBELIUS. Thank you.

The CHAIRMAN. The hearing is adjourned.

[Whereupon, at 11:44 a.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

Hearing Statement of Senator Max Baucus (D-Mont.)
Regarding the Administration's FY2014 Budget and Implementing the Affordable Care Act

Warren Buffett once said, "Price is what you pay. Value is what you get."

This morning, we are here to discuss the health care proposals in the president's fiscal year 2014 budget. As we do, we must determine the value in what we're paying.

Specifically, I want to focus on the value of Medicare and Medicaid. These programs touch the lives of more than 100 million Americans – nearly one in every three citizens.

I also want to examine the progress the administration has made in implementing the health reform law. If the administration implements it correctly, millions more Americans will gain access to health care next year as a result of the law.

These programs fall under the purview of our witness this morning, Secretary Kathleen Sebelius, and the president's budget affects all of these programs. I'm sure you're quite busy, Secretary Sebelius.

In just 167 days, millions of Americans will begin enrolling in health insurance plans in their state's marketplace. Time is short. You need to use each of these days to work with states and make sure the marketplaces are up and running, ready to help uninsured Americans access affordable coverage.

The president's budget requests a total of $5.2 billion for Program Management at the Centers for Medicare & Medicaid Services. Of this, $1.5 billion would be devoted to establishing and supporting the health insurance marketplaces.

I am concerned that not every state, including Montana, will have an insurance marketplace established in time. I want to hear how the money requested in the budget would be used to ensure these marketplaces will be ready to go on day one.

The president's budget also requests $554 million for outreach and education for the health insurance marketplaces.

For the marketplaces to work, people need to know about them. People need to know their options and how to enroll.

I want to hear the administration's outreach plan leading up to the enrollment period which begins on October 1st. I want to know what's been done so far.

I want these new marketplaces to be simple and successful. I want small businesses to focus on job creation, not confusion. More importantly, I want to know the plan moving forward to better communicate the benefits of the Affordable Care Act.

I am worried that a lack of clear information is leading to misconceptions and misinformation about the law. And people generally dislike what they don't understand.

I hear from people on the ground in Montana that they are confused about the health care law. People are worried about the impacts of new rules and how the marketplaces will affect their families and businesses.

I reached out to Steph Larsen, who works in Montana with the Center for Rural Affairs. She has been travelling across my state talking to business groups and consumers about the new marketplaces.

She reported that few people are attending the informational meetings. Those that are often express a lack of understanding about the marketplaces and what they offer.

Steph told my staff, "There is a lot of misinformation out there about how it's all going to work."

This difficulty is compounded by the unknown as to what the marketplaces will look like in Montana and other states.

My constituents don't understand the role of the tax credits because they simply don't have enough information. The administration needs to do a better job.

And it's not just Montanans. A poll last month by the Kaiser Family Foundation found that 57 percent of Americans say they do not have enough information about the law to understand how it will affect them.

The lack of clear information is leading people to turn to incorrect information.

In fact, 40 percent of Americans thought the law establishes a government panel to make end-of-life decisions for people on Medicare. The law does not.

The poll also found that 57 percent of Americans thought the law includes a public option. The law does not.

The administration's public information campaign on the benefits of the Affordable Care Act deserves a failing grade. You need to fix this.

The budget also offers belt tightening measures to address the deficit. The president's budget proposes $379 billion in Medicare and Medicaid spending reductions.

There are some proposals I agree with to cut our debt. For instance, wealthy beneficiaries should pay higher premiums. Also, we shouldn't pay private plans offering Medicare benefits a higher rate than traditional Medicare.

And efforts to root out fraud must be strengthened because every dollar invested fighting fraud generates a 500 percent return in taxpayer money recovered.

But, there are other policies I oppose. I am concerned the proposed level of cuts to nursing homes may be too high and reduce access to care.

I also have concerns over the president's "chained CPI" proposal. Moving to chained CPI not only impacts Social Security. It also reduces payments to some Medicare providers and increases out of pocket costs for some seniors.

Cutting Social Security and Medicare will hit our seniors with a one-two punch. And these chained CPI changes are on top of the $360 billion in cuts to Medicare the president specified in his budget.

Cutting our debt will require compromise. Everyone will need to pitch in, but we can't balance the budget on the backs of America's seniors.

A plan to rein in our budget deficits cannot just be cuts to Medicare, and it cannot just be a package of tax increases. We need a balanced approach that is fair to all Americans.

The administration's budget also recognizes the need to work with Congress to reauthorize the Temporary Assistance to Needy Families or TANF program.

This program is a vital lifeline for our nation's poorest families. I look forward to working with my Finance Committee colleagues to update the TANF program so that it is a more efficient job creator and pathway out of poverty.

I am also happy the budget makes an investment of $5.9 billion in early learning, including child care. This will allow us to make sure over 100,000 more kids start off on the road to success with early education.

Montana families understand the value of a good education and maintaining our responsibilities as parents and good neighbors.

Secretary Sebelius, as we think about these issues and their effect on the budget, let's remember Mr. Buffet's advice. While the price is what we see in the budget, the value of what we receive is what matters.

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STATEMENT OF HON. ORRIN G. HATCH, RANKING MEMBER U.S. SENATE COMMITTEE ON FINANCE HEARING OF APRIL 17, 2013 PRESIDENT'S FISCAL YEAR 2014 HEALTH CARE PROPOSALS

WASHINGTON - U.S. Senator Orrin Hatch (R-Utah), Ranking Member of the Senate Finance Committee, today delivered the following remarks during a Senate Finance Committee hearing examining the President's budget proposal for Fiscal Year (FY) 2014 with Health and Human Services Secretary Kathleen Sebelius:

Last week, the President released his proposed budget for fiscal year 2014. Although the budget was 65 days late, it does not appear that the Administration used that extra time to find ways to address the critical problems facing our country.

Perhaps most significantly, the President's budget fails to address the fundamental challenge of health care entitlement spending in any significant way. What this document lacks in courage, it more than makes up for in the same partisan rhetoric and policies.

Keep in mind, CBO Director Doug Elmendorf has stated that our health care entitlements, Medicare and Medicaid, are our "fundamental fiscal challenge."

Apparently, if this budget is any indication, the Administration isn't interested in taking up this challenge.

Under the President's budget, Medicare and Medicaid spending will reach nearly $11 trillion over the next decade. Annual mandatory health spending will nearly double from $771 billion in 2013 to $1.4 trillion in 2023.

Although we're projected to spend nearly $7 trillion on Medicare over the next ten years, the Hospital Insurance Trust Fund will continue to run significant deficits. According to the 2012 Medicare Trustees Report, the Trust Fund has $5.3 trillion in unfunded liabilities and is expected to be insolvent by 2024.

Under this budget, the fund will continue on its path to insolvency.

The budget also fails to address many problems facing Medicaid, even though we'll spending more than $4 trillion on the program over the next 10 years. Under this budget, federal Medicaid spending as a percentage of GDP will increase by 25 percent from 1.6 percent to two percent over the next decade, thanks to the expansion of the program courtesy of Obamacare.

It is unacceptable that a program that is the biggest line item in most state budgets and is crowding out essential spending in both education and public safety is barely addressed.

All told, we'll spend more than $22 trillion over the next ten years on our major entitlement programs, Medicare, Medicaid, and Social Security. The President's budget would reduce that amount by only $413 billion, or roughly 1.8 percent.

No one seriously disputes that entitlement spending is the main driver of our debts and deficits. Yet, for the most part, this budget has opted to ignore that reality and kick the proverbial can even further down the road.

These programs need serious structural reforms if they're going to be around for future generations.

Entitlement reform is one of the fundamental challenges of our time. It will require a united effort from members of both parties.

Sadly, this budget fails to show this much needed courage.

I hope that we all will be willing to come to the table on serious, structural reforms to our entitlement programs.

I believe the President wants to do the right thing. What we need now is action.

As you may know, in January, I went to the Senate floor and unveiled five bipartisan entitlement reform proposals – five structural reforms to Medicare and Medicaid that have been supported by both Republicans and Democrats in the recent past.

I have put these ideas forward in hopes of starting a bipartisan conversation on entitlement reform.

I have shared these proposals with the President and I am ready and willing to work with him on solutions to these problems. Secretary Sebelius, I look forward to talking with you about these critical issues Thank you, once again, Mr. Chairman.

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STATEMENT OF

KATHLEEN SEBELIUS

SECRETARY

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

ON

THE PRESIDENT'S FISCAL YEAR 2014 BUDGET

BEFORE THE

COMMITTEE ON FINANCE

UNITED STATES SENATE

APRIL 17, 2013

Testimony of
Secretary Kathleen Sebelius
U.S. Department of Health and Human Services
before the
United States Senate
Committee on Finance
April 17, 2013

Chairman Baucus, Ranking Member Hatch, and Members of the Committee, thank you for the invitation to discuss the President's FY 2014 Budget for the Department of Health and Human Services (HHS).

The Budget for HHS provides critical investments in health care, disease prevention, social services, and scientific research in order to create healthier and safer families, stronger communities, and a thriving America.

The President's fiscal year (FY) 2014 Budget for HHS includes investments needed to support the health and well being of the nation, and legislative proposals that would save an estimated $361.1 billion over 10 years. The Budget totals $967.3 billion in outlays and proposes $80.1 billion in discretionary budget authority. With this funding HHS will continue to improve health care and expand coverage, create opportunity and give kids the chance to succeed, protect vulnerable populations, promote science and innovation, protect the nation's public health and national security, and focus on responsible stewardship of taxpayer dollars.

Improving Health Care and Expanding Coverage

Expanding Health Insurance Coverage. Implementation of the Exchanges, also referred to as Marketplaces, will expand access to affordable insurance coverage for more than 25 million Americans. Marketplaces make purchasing private health insurance easier by providing eligible consumers and small businesses with one-stop-shopping where they can compare across plans. New premium tax credits and rules ensuring fair premium rates improve affordability of private coverage. Marketplaces will be operational in 2014; open enrollment begins October 1, 2013 for the coverage year beginning January 1, 2014. The Budget supports operations in the Federal Marketplaces, as well as oversight and assistance to State-based and Partnership Marketplaces.

Beginning in January 2014, Medicaid coverage rules will be simplified and aligned with rules for determining eligibility for tax credits for private insurance in the Marketplaces, and millions of low-income people will gain coverage. The Centers for Medicare & Medicaid Services (CMS) is committed to working with states and other partners to advance state efforts that promote health, improve the quality of care, and lower health care costs.

Also beginning in 2014, consumers will benefit from a number of new protections in the private health insurance market. Most health insurers will no longer be allowed to charge more or deny coverage to people because of pre-existing conditions. These new protections will also prohibit most health insurers from putting annual dollar limits on benefits and from varying premiums based on gender or any factor other than age, tobacco use, family size, or geography. In addition, new plans in the individual and small group market will be required to cover a

comprehensive package of items and services known as Essential Health Benefits, which must include items and services within ten benefit categories. Finally, most individuals choosing to participate in clinical trials will not face limits in health insurance coverage. This protection applies to all clinical trials that treat cancer or other life-threatening diseases.

Expanding Access to Care through Health Centers. The FY 2014 Budget includes $3.8 billion for the Health Centers program, including $2.2 billion in mandatory funding provided through the Affordable Care Act Community Health Center Fund. In FY 2014, 23 million patients will receive health care through more than 8,900 sites in medically underserved communities throughout the nation. The Budget funds 40 new health center sites for the provision of preventive health care services, expanding outreach and care to approximately 1.5 million additional patients.

Improving Patient Safety. HHS is committed to improving patient safety and reducing the risks and harm that patients can encounter. The Budget includes $63 million for patient safety research at the Agency for Healthcare Research and Quality (AHRQ). AHRQ's patient safety research focuses on the risks and harm inherent in the delivery of health care in order to understand the factors that can contribute to adverse events and how to prevent them. In FY 2014, AHRQ will fund projects to address the challenges of health care teamwork and coordination among providers. AHRQ will also support research on how to establish cultures conducive to patient safety in health care organizations. This research will serve as the foundational basis on which patient safety can be improved.

Increasing Access to Mental Health Services

The FY 2014 Budget includes over $1 billion for mental health programs at the Substance Abuse and Mental Health Services Administration (SAMSHA), including the $460 million for the Community Mental Health Services Block Grant. This block grant provides States flexible funding to maintain community based mental health services for children and adults with serious mental illnesses, including rehabilitation, supported housing, and employment opportunities. The Budget also proposes funding within the block grant to encourage States to build provider capacity to bill public and private insurance. This will support States in an effective transition in the first year of the Affordable Care Act, which will include expanded coverage for mental health and substance abuse treatment services.

Expand Prevention and Treatment for Youth and Families. While the vast majority of Americans with a mental illness are not violent, and are in fact more likely to be the victims of violence, recent tragedies have brought to light a hidden crisis in America's mental health system. The Budget addresses these issues by investing $130 million to help teachers and other adults recognize signs of mental illness in students and refer them to help if needed, support innovative state-based programs to improve mental health outcomes for young people ages 16-25, and train 5,000 more mental health professionals with a focus on serving students and young adults.

Helping Families and Children Succeed

In his State of the Union Address, President Obama proposed a series of new investments to create a continuum of high-quality early learning services for children beginning at birth through age five. As part of this initiative, HHS and the Department of Education are working together to make high-quality preschool available to four-year olds from low- and moderate-income families through a partnership with states, expand the availability of high-quality care for infants and toddlers, and increase highly-effective, voluntary home visiting programs to provide health, social, and education supports to low-income families. Specifically, the FY 2014 HHS Budget includes:

Home Visiting. The Budget extends and expands this voluntary evidence-based program that has shown to be critical in improving maternal and child health outcomes in the early years, leaving long-lasting, positive impacts on parenting skills; children's cognitive, language, and social-emotional development; and school readiness. The Budget proposes a long-term $15 billion investment beginning in FY 2015.

Early Head Start—Child Care Partnerships. The Budget proposes $1.4 billion in FY 2014 for new Early Head Start – Child Care Partnerships that will expand the availability of early learning programs that meet the highest standards of quality for infants and toddlers, serving children from birth through age three. In addition to the new Partnerships, the Budget provides $222 million above FY 2012 to strengthen services for children currently enrolled in the program, avoid further enrollment reductions, and support the Head Start Designation Renewal System. Together, these investments total $9.6 billion, an increase of $1.7 billion over FY 2012.

Child Care Quality Fund. The request includes $200 million above FY 2012 in discretionary funds to help states raise the bar on quality by strengthening health and safety measures in child care settings, supporting professional development for providers, and promoting transparency and consumer education to help parents make informed child care choices. In addition to this funding, the Budget provides $500 million above FY 2012 in mandatory funds to serve 1.4 million children, approximately 100,000 more than would otherwise be served.

Child Support and Fatherhood Initiatives. Additionally, the Budget includes a set of proposals to encourage states to provide child support collections to families rather than retaining those payments. This effort includes a proposal to encourage states to provide all current monthly child support collections to Temporary Assistance for Needy Families recipients. Recognizing that healthy families need more than just financial support alone, the proposal requires states to include parenting time provisions in initial child support orders, to increase resources to support, and facilitate non-custodial parents' access to and visitation with their children. The Budget also includes new enforcement mechanisms that will enhance child support collections.

Protecting Vulnerable Populations

Addressing the Unique Needs of Communities. The Administration for Community Living (ACL) was formed in April 2012 as a single agency designed to help more people with

disabilities and older adults have the option to live in their homes and participate fully in their communities. The FY 2014 Budget reflects the creation of ACL by bringing together the resources for the Administration on Aging, the Office on Disability, and the Administration on Intellectual and Developmental Disabilities, into a consolidated request. This newly organized agency works across HHS to harmonize efforts to promote community living, which can both save federal funds and allow people who choose to live with dignity in the communities they call home. ACL's Lifespan Respite Care program, as an example, focuses on providing a test bed for needed infrastructure changes and on filling gaps in service by putting in place coordinated systems of accessible, community-based respite care services for family caregivers of children and adults with special needs.

Promoting Science and Innovation

Advancing Scientific Knowledge. The FY 2014 Budget includes $31.3 billion for the National Institutes of Health (NIH), an increase of $471 million over the FY 2012 level, reflecting the Administration's priority to invest in innovative biomedical and behavioral research that spurs economic growth while advancing medical science. In FY 2014, NIH will focus on investing in today's basic research for tomorrow's breakthroughs, advancing translational sciences, and recruiting and retaining diverse scientific talent and creativity. Investment in NIH also helps drive the biotechnology sector and assure the nation's place as a leader in science and technology.

Alzheimer's Disease Initiatives. The Department continues to implement the National Plan to Address Alzheimer's Disease, as required by the National Alzheimer's Project Act. In FY 2014, the Budget includes a $100 million initiative targeted to expanding research, education, and outreach on Alzheimer's disease, and to improving patient, family, and caregiver support. Included in this initiative is $80 million within the NIH budget to be devoted to speeding drug development and testing new therapies. Also, the request for the Prevention and Public Health Fund (Prevention Fund) includes $20 million for the Alzheimer's Disease Initiative. Of this, ACL will use $15 million to strengthen state and local dementia intervention capabilities and for outreach to inform those who care for individuals with Alzheimer's disease about resources available to help them. HRSA will use the other $5 million to expand efforts to provide training to healthcare providers on Alzheimer's disease and related dementias.

Focusing on Responsible Stewardship of Taxpayer Dollars

Contributing to deficit reduction while maintaining promises to all Americans. The HHS Budget makes the investments the nation needs right now, while reducing the deficit in the long term and ensuring the programs that millions of Americans rely on will be there for generations to come. Already, we have seen how our programs are making a difference to reduce the deficit. The Affordable Care Act has helped to slow rising costs by building a smarter system to get at the underlying health care costs that have been driving Medicare and Medicaid spending. In fiscal year 2012, per beneficiary Medicare spending grew by only 0.4 percent, and total per beneficiary Medicaid spending actually decreased – by 1.9 percent. For the 1st time in a decade, overall health care costs grew more slowly than the economy. We are driving down costs while improving quality for patients by building a smarter system – for example, after decades stuck at

19 percent, avoidable hospital readmissions fell to 17.8 percent in Medicare last year. The Budget helps HHS to build on this work.

The Budget maintains ongoing investments in areas most central to advancing the HHS mission while making reductions to lower priority areas, reducing duplication, and increasing administrative efficiencies. Overall, the FY 2014 Budget includes nearly $2.3 billion in discretionary terminations and budget reductions.

The specified Medicare and Medicaid legislative proposals in the FY 2014 Budget seek to reduce the deficit while encouraging economic growth and maintaining the administration's commitment to HHS programs upon which tens of millions of Americans depend. Medicare savings would total $371.0 billion over 10 years by encouraging beneficiaries to seek value in their health care choices; strengthening provider payment incentives to promote high-quality, efficient care; and increasing the availability of generic drugs and biologics. The Budget also includes $22.1 billion in savings over 10 years to make Medicaid more flexible, efficient, and accountable while strengthening Medicaid program integrity. Together, the FY 2014 discretionary budget request and these legislative proposals allow HHS to support the Administration's challenging yet complementary goals of investing in the future and establishing a sustainable fiscal outlook.

Combating fraud, waste, and abuse in health care: The FY 2014 Budget makes cutting fraud, waste, and abuse a top Administration priority. In addition to the base discretionary Health Care Fraud and Abuse Control (HCFAC) funding in FY 2013 and FY 2014, the Budget seeks new mandatory funding to support these efforts. Starting in FY 2015, the Budget proposes all new HCFAC investments be mandatory, consistent with levels in the Budget Control Act. This investment supports fraud prevention initiatives like the Fraud Prevention System and screening for Medicare providers and suppliers to reduce improper payments in Medicare, Medicaid and CHIP; and HHS-Department of Justice Health Care Fraud Prevention and Enforcement Action Team initiatives, including the Medicare Strike Force teams and the Fraud Prevention Partnership between the federal government, private insurers, and other key stakeholders.

From 1997 to 2012, HCFAC programs have returned over $23 billion to the Medicare Trust Funds, and the current three-year return-on-investment of 7.9 to 1 is the highest in the history of the HCFAC program. The Budget's 10-year HCFAC investment yields a conservative estimate of $6.7 billion in Medicare and Medicaid savings.

The Budget includes $389 million in discretionary and mandatory funding for the Office of Inspector General (OIG), an increase of $101 million above the FY 2012 level. This increase will enable OIG to expand CMS Program Integrity efforts for the Health Care Fraud Prevention and Enforcement Action Team and improper payments, and also enhance investigative efforts focused on civil fraud, oversight of grants, and the operation of Affordable Care Act programs.

The Budget also includes $82 million for the Office of Medicare Hearings and Appeals (OMHA), an increase of $10 million from FY 2012, to address OMHA's adjudicatory capacity and staffing levels and maintain quality and accuracy of its decisions. The increase allows

OMHA to establish a new field office in the Central time zone supported by additional Administrative Law Judge teams and attorneys, and operational staff.

Performance, Evaluations and Effectiveness

Assessing the Impact of Health Insurance Coverage Expansions on Safety Net Programs. The Budget includes $3 million to the Assistant Secretary for Planning and Evaluation to evaluate the impact of health insurance coverage and benefit expansions among beneficiaries of HHS direct service programs. This request supports the continuation of research and evaluation studies, collection of data, and assessments of the costs, benefits and impacts of policies and programs under consideration by HHS or the Congress. This data will inform decisions about how to tailor policies and programs to align with new coverage options and support available starting in 2014.

Thank you for the opportunity to testify. I will be happy to answer any questions you may have.

Responses to Questions for the Record from Secretary Sebelius
United States Senate Committee on Finance
Public Hearing
"The President's Budget for Fiscal Year 2014"
April 17, 2013

Senator Baucus:

Quality Measures for Children

The Children's Health Insurance Program (CHIP) Reauthorization Act of 2009 included guidelines and funding to develop health care quality metrics for children. The Department of Health and Human Services (HHS) has made significant progress since then – a wide range of measures have been developed and a core set has been identified for state reporting. Ideally, Medicaid should follow in Medicare's footsteps and gradually link payment to quality, but states are in the early reporting stages so far. Additional work – at both the legislative and regulatory levels – needs to be done to move forward with paying for quality.

1. **What are the necessary steps to moving toward quality-based payment in Medicaid and CHIP? How can we partner together to make that goal a reality?**

Answer: An important step toward quality-based payment in Medicaid and CHIP is to first measure and assess quality in a standardized format. CMS has a number of initiatives underway towards achieving this goal. We have released the Initial Core Set of Child Health Care Quality Indicators for Medicaid and CHIP, which includes a range of children's quality measures encompassing both physical and mental health, including chronic conditions such as asthma and diabetes. CMS' Pediatric Quality Measures Program and the Pediatric Electronic Health Record Format also represent initiatives the agency is pursing to help provide us with important data from states about areas for targeted growth and improvement. Additionally, the Affordable Care Act created a new opportunity for states to measure health care quality for adults in Medicaid. In 2012 CMS published the Initial Core Set of Health Quality Measures for voluntary use by state Medicaid agencies. The program established a set of quality measures and a standardized reporting format for them. In January 2013, CMS established the Adult Quality Measurement program to fund the development, testing, and validation of emerging and innovative evidence-based adult health quality measures.

With work well underway on developing quality measures for Medicaid and CHIP beneficiaries, we are building on this foundation by partnering with many states to better reimburse for quality improvement for Medicaid and CHIP beneficiaries. Under State Plan options as well as demonstration authority, CMS is actively partnering with multiple states to implement payment methodologies that reward providers for quality improvement and achievement (e.g., improving patient care outcomes, focusing on person centered care, and using electronic health records). CMS supports these efforts through existing Health Home authority, expanded efforts under 1115 authorities to support delivery reform, efforts in long term care, and collaborations within the agency. Additionally, CMS released two State Medicaid Director letters (http://www.medicaid.gov/Federal-Policy-Guidance/downloads/SMD-12-001.pdf;

http://www.medicaid.gov/Federal-Policy-Guidance/downloads/SMD-12-002.pdf) that describe new options CMS has made available to states to support efforts to better integrate care and reimburse for patient outcomes, including options to implement shared savings. We are also refining our monitoring and evaluation efforts so that we can continually adjust these efforts to improve quality for our beneficiaries.

As we partner with states, CMS will continue to enhance reporting on quality measures and partner with states to develop payment systems that integrate the quality of care provided to Medicaid and CHIP beneficiaries.

Improving the TANF Program

We were pleased to see that the Administration's Budget indicates a willingness to work with Congress to reauthorize the TANF program. We agree that reauthorization is overdue.

2. **What would you suggest to create a TANF program that is responsive in all states and helps states to continue to focus on employment, even in periods of high unemployment?**

Answer: The Administration looks forward to engaging in a dialogue with Congress and stakeholders to develop a TANF program that is well-prepared to respond to future economic events and help parents successfully prepare for, find, and retain employment. The Administration believes that in order to strengthen TANF's effectiveness in helping families achieve self-sufficiency, reauthorization should include performance indicators that drive program improvement and ensure that states have the flexibility to engage recipients in activities that promote success in the workforce, including families with serious barriers to employment. The Administration will also be prepared to work with Congress to revise the Contingency Fund to make it more effective during economic downturns.

3. **The President proposes to pay for the Supplemental Grants permanently by reducing the Contingency Fund. Both programs are important. Have you considered alternative proposals? What about a combined fund that would create access for more states?**

Answer: The Administration agrees that both the Supplemental Grants for Population Increases and the Contingency Fund provide important resources to state TANF programs and are open to dialogue about the best way to structure them going forward. We have proposed to extend the Supplemental Grants because these grants were originally created to provide adjustments for those states anticipated to have more rapid population growth or that had lower block grant funding levels per needy individual, and we believe it is appropriate to maintain those adjustments.

The loss of supplemental grant funding has had an adverse effect on services to needy families in the affected states. According to states, the loss of supplemental grants has led to cuts in such areas as kinship care, basic assistance, and modest clothing allowances for school-age children.

Employer Outreach

Enrollment for health insurance coverage for 2014 will begin October 1, 2013 which is when the Marketplaces need to be up and running. Employers play a crucial role in Marketplace implementation. Employers receive rules and guidance from not only HHS, but other federal agencies such as the Internal Revenue Service and Department of Labor. Employers must navigate a multitude of rules and decisions to be ready for 2014.

The Finance Committee takes seriously the importance of implementing the Affordable Care Act the right way for consumers and employers. Importantly, the Administration must work with employers across the U.S. to ensure they are ready and able to implement the Affordable Care Act. I have heard from small business owners in Montana that they need more clarity and tools to get ready for the Marketplaces and implement the Affordable Care Act.

4. Please share with the Committee what the Administration is doing to help employers implement the Affordable Care Act and get ready for 2014.

Answer: The Administration has taken a number of steps to help employers implement the Affordable Care Act. For example, the Small Business Health Options Program (SHOP) Marketplaces will help small businesses provide affordable, quality coverage for their employees. Eligible small businesses will be able to access tax credits and obtain access to information about coverage options through the SHOP. By pooling small employers together, reducing transaction costs, and increasing transparency and competition, the SHOP Marketplace will be more efficient and competitive.

CMS has already released the draft SHOP applications for small employers and employees and has begun engaging the small business community to hear their input and communicate how the SHOPs will work, when they will be ready, and what updates there are on policy and regulations. These discussions, which are led by CMS regional offices, are the start of ongoing conversations with all stakeholders including the small business community. CMS has worked with our regional offices and the Small Business Administration to provide updates to small businesses on recent policies and regulations. We held meetings in March – in Dallas, TX and Atlanta, GA – and look forward to working with other regional offices to provide more specific information on the impact of the Affordable Care Act on small businesses. CMS has also been developing SHOP-focused training and materials to help small businesses understand the Affordable Care Act and the opportunities it presents to them. In addition, the Small Business Administration has created its own education materials and conducted training for small businesses. We also expect agents and brokers to play a significant role in working with the small business community.

The Affordable Care Act does not impose a penalty on small employers of fewer than 50 full-time equivalent employees that do not offer health insurance. Rather, it creates the SHOP Marketplace specifically to help ease the burden on small businesses of providing health insurance to their employees, through a tax credit for eligible employers that took effect in 2010. Starting in 2014, the tax credit will be available only to employers who obtain coverage for their employees through the SHOP. The CBO estimates that these tax credits may save small businesses $40 billion between 2010 and 2019. The Council of Economic Advisors estimates that 4 million small businesses are eligible for the credit if they provide health care to their workers. Beginning January 1, 2014 this credit is worth up to 50 percent of a small business's premium costs.

5. How is your department coordinating with other relevant parts of the government, like the IRS and the Labor to guide and offer support for employers in Exchange implementation?

Answer: As you know, starting in 2014, small businesses with generally fewer than 50 employees will have access to a Small Business Health Options (SHOP) Marketplace—a new, transparent, competitive marketplace where they can shop for affordable, qualified health benefit plans to offer their employees. This gives small businesses buying power similar to what large businesses have to get better choices and lower prices for employee coverage.

Since the Affordable Care Act was signed into law, the Department of Health and Human Services (HHS) has been working closely with the Departments of Labor and Treasury, and other federal agencies, to ensure that small businesses, states and other stakeholders have had input into the development of the SHOP. As each Department has responsibility for enforcement of various sections of the law, we have worked jointly to develop policies, issue rules and guidance, and develop outreach and enrollment plans that affect small businesses.

HHS has been developing SHOP-focused training and materials to help small businesses understand the Affordable Care Act and the opportunities it presents to them. We have a strong partner in the Small Business Administration, which has created its own education sessions for small businesses. Through our regional offices, HHS and the Small Business Administration have been providing updates to small businesses on recent policies and regulations. HHS has also released the draft SHOP applications for employers and employees and has begun engaging small business to hear their input and communicate important dates and provide implementation updates related to the SHOP Marketplace.

Consumer Operated and Oriented Plans (CO-OPs)

The Affordable Care Act (ACA) created the CO-OP program to offer low-interest loans to eligible groups to help set up and maintain health plans. CO-OPs are directed by their customers and designed to offer individuals and small businesses additional affordable, health insurance options. Starting January 1, 2014, CO-OPs will be able to offer health plans through the Exchange. To date, a total of 24 non-profits offering coverage in 24

states have been awarded $1,980,728,696. Montana is participating in the CO-OP program, through the Montana Health Cooperative. Montana Health Cooperative is sponsored by a coalition of small businesses and community leaders and plans to add a strong primary care capacity to Montana's rural and medically underserved communities. Montana Health Cooperative will provide health insurance coverage statewide.

Madam Secretary, the Affordable Care Act created the CO-OP program as additional coverage option to increase competition on the Exchange. CO-OPs are directed by their customers and designed to offer affordable health insurance to consumers and small businesses.

6. Please share with the Committee the progress of the approved CO-OPs.

Answer: To date, 12 CO-OP loan recipients have received a license to sell insurance from their respective state insurance regulators, and another four have received conditional approval to sell insurance. Licensed CO-OPs are now eligible to submit their proposals to offer qualified health plans through the Marketplace.

Achieving state licensure is a significant milestone for new health insurance issuers like CO-OPs preparing to enter the market. As noted by the American Medical Association and others, health insurance markets are increasingly concentrated, leaving consumers and health care providers with fewer choices. We believe that CO-OPs offer an important option to Americans buying insurance in the individual and small business markets. For small businesses and individuals, CO-OPs will provide a new choice and opportunity for payers and patients to work together to create coverage and care that is both more efficient and higher quality. Competition and choice are important tools in making health care more affordable and improving the quality of care.

7. Many state CO-OPs, including some represented by my Committee colleagues, were well into negotiations with HHS when this decision was made. How is HHS continuing to work with these unapproved CO-OPs?

Answer: To date, 24 private nonprofit entities have been awarded loans to establish CO-OPs across 24 states. Because such funds are considered to be obligated when the awards are made upon execution of a loan agreement, loan or grant awards issued to CO-OPs prior to enactment of the American Taxpayer Relief Act of 2012 are not subject to or affected by the rescission. HHS will continue to provide assistance and oversight to these CO-OPs as they work to achieve program milestones, receive licensure from their respective state Departments of Insurance, qualify as a Qualified Health Plan, and prepare to participate in the new Health Insurance Marketplace.

HHS no longer has the authority to make loan awards to new borrowers. This applies to both new applications and applications received, but not awarded, during earlier application rounds. We are encouraging denied CO-OP applicants to work with CO-OP associations, existing CO-

OP loan recipients, insurance regulators, and other stakeholders to determine what role they can play in the reformed 2014 marketplace.

Marketplace Readiness

A very important provision of the ACA was the creation of health insurance Marketplaces (also known as Exchanges). These Marketplaces, where individuals can compare and shop for health insurance, need to work seamlessly come 2014 if the law is to be considered a success. Consumer outreach and branding are essential to ensuring people are aware of their options and able to enroll in these new Marketplaces.

Madame Secretary, as you know, the Marketplaces are critical to ensuring access to affordable health care coverage for all Americans. It is vital that they are up and running on time so people can compare plans and shop for health insurance.

8. What is your plan to ensure Marketplaces are successfully implemented and ready to go?

Answer: We are moving forward with Marketplace implementation for open enrollment beginning on October 1, 2013. We are also working with states to provide the maximum amount of flexibility to enable them to perform the functions in their Marketplaces. A number of different systems will be in place by October 1 to accommodate open enrollment, including IT, a call center, and plan management systems, and we are carrying out the plans we have in place to implement these systems.

We are also developing mitigation strategies for IT systems as provided in the guidance established by the National Institute of Standards and Technology, Special Publication 800-34, revision 1 (May 2010). The document provides guidance to help personnel evaluate information systems and operations to determine mitigation strategy requirements and priorities.

CMS and our state partners are working hard to ensure that people are aware of the new tools that will soon be available to them. On www.HealthCare.gov, people can learn about the Affordable Care Act, review health insurance basics, such as understanding what their coverage costs, and access an interactive checklist to help prepare them to shop for coverage in the new Marketplaces. CMS also expects that other Federal agency partners and members of the private sector will be involved in efforts to reach, engage, and assist potential enrollees.

9. Do you have enough funding to get this very important job done to ensure consumers everywhere have the same experience?

Answer: In FY 2014, the President's Budget requests $1.5 billion in budget authority for costs related to Marketplaces including operations of a Federally-facilitated Marketplace (FFM) in each state that will not have its own operational Marketplace by January 1, 2014, oversight of State-based and Partnership Marketplaces, and to carry out the Secretary's duties on behalf of all

Marketplaces, such as operation of a data services hub. These functions will be operational in FY 2014 beginning with open enrollment on October 1, 2013. In addition, CMS will collect user fees from all issuers offering qualified health plans in the FFMs starting in January 2014.

Rural Health

The Affordable Care Act (ACA) created a number of delivery system reform demonstrations and established a Center for Medicare and Medicaid Innovation (CMMI) within CMS. These demonstrations are intended to test and evaluate new models to reduce Medicare and Medicaid spending while preserving or enhancing the quality of care. CMMI is running a number of demonstrations, but has performed few in rural areas.

10. Can some of the demonstrations HHS is currently conducting be adapted to work in rural areas?

Answer: We know that we have to change the incentive structure of our payment systems to emphasize care coordination, improve quality, and reduce the total cost of care, especially in rural areas that are often underserved. The Innovation Center has worked very hard to ensure that its models have geographic distribution so that each model is tested in a variety of communities nationwide.

For example, the Adams County Health Center in Idaho is one of several rural participants in the Federally Qualified Health Center (FQHC) Advanced Primary Care Practice Demonstration, which is testing enhanced support to FQHCs to help them achieve medical homes. The Adams County Health Center is in a medically underserved rural area, with only about three thousand residents in a thousand square mile service area. Also, the Mountain Area Health Education Center, serving a rural area in Western North Carolina, received a Health Care Innovation Award to test team-based primary care for patients with chronic pain.

We also developed the Advance Payment Accountable Care Organization (ACO) model specifically for entities such as physician-based and rural providers with less access to capital to help increase the participation in the Shared Savings Program by these groups.

11. Is HHS developing any ideas aimed at improving health care provided in frontier areas like Montana?

Answer: We are currently developing the Frontier Community Health Integration Demonstration Program with input from the Health Resources and Services Administration. This demonstration is for very small critical access hospitals with an inpatient census of less than five in sparsely populated states.

We believe that medical homes may have the potential to improve health care provided in frontier areas. Several of the Health Care Innovation Awards are testing medical home models. For example, two awards were given to organizations to test medical homes that focus on

integrating primary and behavioral health care. These medical homes are being tested in several frontier areas, including Montana, North Dakota, and South Dakota. The Health Care Innovation Awards are still in their early stages and we do not yet have any results, but we anticipate that the results may inform future Medicare and Medicaid payment policy.

Recognizing that rural stakeholders may have difficulty meeting some of the requirements of the initiatives and our continual efforts to engage these communities, we have formed an HHS Workgroup to gather ideas from stakeholders to find new models that might be appropriate for rural communities.

Senator Hatch:

Coordinated Care

The ability for a physician to own imaging, physical therapy or pathology services is an excellent example of coordinated care and contributes to quality, access and timeliness of care for those on Medicare and Medicaid. Beneficiaries generally get treatment the same day in the same office often while hospitals are some distance away with completely different staff and a completely new set of forms. The President's Budget may prevent some of these services from being offered by physicians who own them, unless the practice meets certain accountability standards as defined by the Secretary of HHS, which may put obstacles in the way of effective integrated care.

1. **What is the basis for this proposal, what assumptions were made to come up with the score of $6 billion?**

Answer: The estimate of $6 billion in savings over 10 years was developed by the independent CMS Office of the Actuary based on its assumptions about predicted reductions in spending on services and behavioral changes related to the policy.

2. **What are some specific examples of "accountability standards," and how might these be implemented?**

Answer: This proposal allows the Secretary flexibility to determine these standards, which would be done through a rulemaking process. Factors that could be considered include quality, value, efficiency, utilization, and access.

Medicaid Drug Rebate

The Patient Protection and Affordable Care Act (PPACA) revised the formula for Medicaid drug rebate calculations for products considered line extensions, which was intended to address new medicines that could be considered line extensions or new

formulations. The President's Budget proposes to change the alternative rebate for new formulations in a way that seems to effectively increase rebate payments for these drugs. As you know, new formulations are often an effective way to increase patient medication adherence resulting in better patient health and lower systemic costs.

3. **If an overly broad definition of new formulations and an increased alternative rebate for these types of products were to become the new policy, might this actually deter the development of innovative products that could improve or even save the lives of patients with critical conditions?**

Answer: The definition of line extension drugs in the proposed rule for Medicaid-covered outpatient drugs, which was issued in February 2012, proposed to define a line extension drug as a "single source or innovator multiple source drug that is an oral solid dosage form that has been approved by the FDA as a change to the initial brand name listed drug in that it represents a new version of the previously approved drug, such as a new ester, a new salt, or other non-covalent derivative; a new formulation of a previously approved drug; a new combination of two or more drugs; or a new indication for an already marketed drug." CMS received many timely comments on this proposal and we are carefully considering these as we work to finalize our policy.

The President's FY 2014 budget proposal to correct the ACA Medicaid Rebate Formula for New Drug Formulations makes a technical correction to the Affordable Care Act provision that imposes an alternative inflation-based rebate formula for line extension drugs. The unit rebate amount (URA) calculation for brand-name drugs includes the basic rebate amount plus an additional rebate amount. However, the current rebate calculation for line extension drugs leaves out the basic rebate amount for line extension drugs; this proposal revises the statute to include the basic rebate amount. (The basic URA for brand drugs is the greater of 23.1% of AMP, or the difference between AMP and the best price per unit, adjusted for CPI-U.)

<u>Medicare Advantage</u>

The Administration just released its final rate notice regarding Medicare Advantage payments for calendar year 2014. While we were pleased to see the final rates assumed a "fix" to the sustainable growth rate, there are many other challenges that Medicare Advantage plans will face in 2014. For example, plans will have to comply with new medical loss ratio restrictions, the premium tax, and major changes to the CMS-HCC risk adjustment methodology.

4. **When plans are adapting to so many new requirements and payment cuts, why does the Administration believe that additional cuts – in coding intensity adjustments and employer group waiver plans – are appropriate at this time?**

Answer: The legislative proposals in the President's FY 2014 Budget related to coding intensity adjustments and MA employer group waiver plans (EGWPs) are designed to improve the accuracy of MA payments.

The proposal to increase the MA minimum coding intensity adjustment would improve the accuracy of statutorily required risk adjustment of MA payments that accounts for the health status of each MA-enrolled beneficiary. MA plans tend to submit both more diagnosis codes and higher levels of diagnosis codes for beneficiaries with similar underlying health status than providers in FFS (and this difference between MA and FFS diagnosis codes increases over time). Because of this difference in coding, the statute requires that CMS institute a "coding intensity adjustment for MA plans. The coding intensity adjustment is applied as a downward adjustment to beneficiaries' risk scores in each MA plan. In a March 2013 report the Government Accountability Office estimates that the coding intensity adjustment has been insufficient to account for the differences in coding between MA plans and fee-for-service Medicare.[1] This budget proposal is consistent with the GAO recommendation and reduces overpayments to plans resulting from coding pattern differences between MA and Medicare FFS providers.

The President's FY 2014 budget also proposes to set the base MA payment amount for EGWPs in each county using the average standardized bid for individual plans in the county. EGWPs contract directly with employers and therefore have different bidding incentives from individual MA plans. CMS has found in recent years that the projected average risk scores for EGWP members were lower than for individual MA plan enrollees. However, the average EGWP bids were higher than those for individual MA plans. The Medicare Payment Advisory Commission (MedPAC) also believes that payments for EGWPs could be made more accurate. The proposal would align MA payment policy for EGWPs more closely with Part D payment policy, which sets Part D payments to EGWPs based on the national average Part D bid amount and the national base beneficiary premium, not on Part D bids submitted by EGWPs. EGWP payments in both Parts C and D will be established on a set, prospective basis rather than letting EGWPs bid for their Part C payment level.

5. Please share what impact you believe these policies may have on Medicare Advantage enrollment and on benefits offered to Medicare Advantage enrollees.

Answer: The Medicare Advantage (MA) program has remained a strong and viable option for Medicare beneficiaries since passage of the payment reforms in the Affordable Care Act. We expect the program will continue to be a viable option if these policies are enacted. MA premiums for 2013 are stable, increasing less than a $1.50 from last year. As of February 2013 total MA enrollment is 14.1 million, up from approximately 13 million in 2012. Beneficiary access to the MA program also remains strong, with 99.6 percent of beneficiaries having access to a MA plan. MA plan benefits have also remained stable since passage of the Affordable Care Act.

RACs

6. Does HHS have a policy to ensure that RACs and other anti-fraud activities, while necessarily rigorous, do not place undue burdens on providers?

[1] http://www.gao.gov/assets/590/587637.pdf

Answer: We balance our responsibilities to protect taxpayer money from fraud and abuse, while ensuring that we have a good working relationship with our provider partners by avoiding unnecessary burdens or restrictions. We have a series of programs aimed at fighting fraud – RACs are a part of that portfolio, as directed by Congress. We are constantly refining that portfolio, so that our goals and actions are coordinated and aligned.

As a part of that continual refinement, we are working to ensure that all letters issued by any Medicare review contractor are in the same format with a detailed review rationale, provider due dates and deadlines are consistent, and audits are effective and efficient. Claims that are currently under review by other Medicare review contractors are excluded from review by the RACs. This helps ensures that multiple contractors are not reviewing the same claim. Additionally, RACs are not allowed to reopen a claim after three years have passed. The RACs are also subject to medical record limits based on provider type, size and duration of their reviews.

7. Has CMS examined the impact, including costs to the agency, of audits that are overturned at the ALJ level?

Answer: By virtue of CMS's oversight that ensures Recovery Auditors make accurate improper payment decisions, we continually strive to reduce the appeal rate, which, in turn, decreases provider burden and administrative costs. The FY 2011 Recovery Audit Report to Congress reported that more than 90 percent of Recovery Audit overpayment determinations were not appealed, and that just 2.9 percent of all Recovery Auditor overpayment determinations were overturned on appeal.

CMS has multiple layers of oversight and incentives to ensure Recovery Auditors make accurate payment decisions. Every month, for example, CMS, through an independent review contractor, reviews a random sample of claims from each Recovery Auditor to determine an accuracy rate representing how often the Recovery Auditors accurately determine overpayments or underpayments. The Recovery Auditors' accuracy scores are consistently above 90 percent. CMS reports appeal statistics in the annual Report to Congress and on its website at: www.cms.gov/rac. Moreover, Recovery Auditors are required to return any contingency fee if an improper payment is overturned.

The Office of Medicare Hearings and Appeals oversees Medicare appeals at the Administrative Law Judge level and information on ALJ appeals can be found in the FY 2014 HHS Congressional Budget Justification http://www.hhs.gov/budget/fy2014/secretary-congressional-justification.pdf

General appeals statistics for RACs are available for download under "Appeal Fact Sheets" on the CMS website at: http://www.cms.gov/Medicare/Appeals-and-Grievances/OrgMedFFSAppeals/RedeterminationbyaMedicareContractor.html

Mental Health

8. When will HHS finalize the Interim Final Rule on the Wellstone/Domenici Mental Health Parity and Addiction Equity Act?

Answer: The Administration intends to issue the final rule on the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act (MHPAEA) by the end of CY 2013.

Senator Burr:

BARDA and BioShield

As you know, after 9/11, Congress created BioShield to encourage the development of countermeasures for identified CBRN threats by providing assurances that the federal government was committed to procuring products necessary to protect Americans. A few years later, we created the Biomedical Advanced Research and Development Authority – BARDA- to further speed the development of necessary medical countermeasures. The headlines in recent days serve as an important reminder that we must be prepared for the full range of threats that may arise, whether man-made like a terrorist attack or the result of mother-nature, such as an influenza pandemic. The PAHPA Reauthorization bill signed into law earlier this year authorized $415 million a year for BARDA and $2.8 billion for BioShield over a five year period. It is important that we aggressively support the development of medical countermeasures, which can take up to a decade and cost hundreds of millions of dollars. Supporting BARDA and BioShield at their authorized level is a matter of national security.

I'm pleased that the President's budget proposes funding BARDA at its authorized level, but I'm concerned that it proposes only $250 million for BioShield as the first installment of a multi-year commitment.

1. What does such a multi-year commitment look like in the opinion of the Administration? Please answer this question in detail.

Answer: Over the next five years, BARDA plans to procure 12 new products for anthrax vaccine, small pox antiviral, treatments for the exposure to radiological and nuclear devices and biodosimetry devices for quantifying the exposure, broad-spectrum antimicrobials, and chemical antidotes. The opportunity to procure these maturing candidate-products is a direct result of the robust Advanced Research and Development pipeline built by BARDA over the past seven years. There are now over 80 products in development.

With the continued congressional support for Project BioShield and additional investments in the coming years consistent with levels of funding authorized in the *Pandemic and All-Hazards Preparedness Reauthorization Act (*PAHPRA), BARDA anticipates procuring 12 new MCM products between FYs 2014 and 2018, which will greatly enhance our Nation's state of

preparedness. New MCMs emanating from the current BARDA development pipeline and mature enough for procurement under BioShield and utilization in an event under the Emergency Use Authorization (EUA) from FYs 2014-2018 include the following:

- Multiple next generation artificial skin replacement therapy for definitive care treatment of thermal and radiation burns;
- Antimicrobial drug-impregnated mesh dressings for point-of-care treatment of thermal and radiation burns;
- Gene expression- and other technology-based biodosimetry devices for quantitative measurement of ionizing radiation exposure in affected persons following a nuclear event;
- Multiple chemical antidotes for cyanide poisoning and highly-volatile nerve agents;
- Multiple therapies using cell-based, recombinant protein, and small molecule technologies for treatment of hematopoietic, skin/lung, and gastrointestinal illnesses associated with acute radiation syndrome (ARD);
- Multiple broad spectrum antibiotics for treatment of anthrax, plague, tularemia, and other biothreats; and
- Next-generation recombinant protective antigen anthrax vaccine

2. Should we expect future budgets to propose $250 million a year, or amounts that are consistent with fulfilling BioShield's authorized amount?

Answer: The FY 2014 President's Budget reflects BARDA's financial need for procurements through Project BioShield for that fiscal year. BARDA's planning includes three awards in FY 2014 including:

- Purchase a new artificial skin replacement therapy for definitive care treatment of thermal and radiation burns experienced in persons exposed to a nuclear or other fire event.
- Replenish the existing stockpile of smallpox vaccine for immunocompromised persons.
- Pay maintenance costs for a vendor-managed inventory of anti-neutropenia cytokines used to treat persons exposed to high amounts of ionizing irradiation.

BARDA develops substantial out year planning for both advanced research and development and procurement. Those estimates are included in the Department's multiyear budgeting initiative that began following the 2010 PHEMCE Review. As required in PAHPRA, a report of the multiyear budgeting initiative will be available to Congress on an annual basis. Assuming current progress, BARDA expects to procure 12 new products between FY 2015 and 2018;

procurement funding may be commensurate with the authorized funding level for Project BioShield in current law.

Medicaid Provider Taxes

The past two years, the President's budgets proposed reforms to the Medicaid provider taxes. The President's Fiscal Commission recommended eventually eliminating Medicaid provider taxes because it is seen as a gimmick to draw down an increased federal match. As you know, reforming Medicaid provider taxes can produce billions in federal savings.

3. Why does this year's budget not include any proposal on this issue, despite the billions it would save in federal spending?

Answer: The Administration's Medicaid proposals will ensure stability in the Medicaid program while states implement the Affordable Care Act's coverage expansion in 2014. The Budget proposes to save Medicaid $22 billion over ten years without harming beneficiaries, and at the same time promoting program integrity and increasing efficiencies in Medicaid. These savings come from proposals to extend reductions to Medicaid DSH payments, clarify Medicaid's drug rebates and payments, align Medicaid DME payments with the rates paid by Medicare, and strengthen the Department's ability to fight fraud, waste, and abuse in Medicaid.

NIH Funding

The President's FY 2014 budget proposes funding for the National Institutes of Health, including $40 million on the new Brain Research through Application of Innovative Neurotechnologies, the BRAIN Initiative, and an additional $80 million in research on Alzheimer's disease. The budget states that funds for these initiatives are coming from within NIH.

4. Please provide more specific details regarding from which specific programs or Institutes the proposed funding is expected to come.

Answer: *BRAIN Initiative*: Nearly half of the FY 2014 NIH funds proposed for the BRAIN Initiative will be provided by the Office of the Director (OD) and the NIH Blueprint for Neuroscience Research. NIH Institutes and Centers (IC) are also committed to expanding the opportunities for new avenues of basic research and are contributing the remainder of funds to this project. The specific funding breakdown is as follows:

NIH OD	$10 million
NIH Blueprint for Neuroscience Research	$10 million
NIMH	$7.5 million
NINDS	$7.5 million
NIDA	$4 million
NIBIB	$1 million

Alzheimer's Disease: The proposed $80 million for Alzheimer's research in the FY 2014 President's Budget is part of the $471 million increase in total funding over the FY 2012 level, reflecting the "Administration's priority to invest in innovative biomedical and behavioral research that spurs economic growth while advancing medical science." This funding is requested for the National Institute on Aging.

HIT

Last week, I joined several of my colleagues in highlighting concerns with the state of health IT adoption and the need for increased oversight and accountability of the Administration's implementation of the HITECH provisions. The President's budget proposes a new user fee for the Office of the National Coordinator for Health Information Technology, but provides no specific details regarding this user fee.

5. Please provide specific details regarding the proposed user fee for ONCHIT, including how the user fee would be assessed and what it would be used to fund.

Answer: Many stakeholders, including health IT developers, hospitals, clinicians and members of Congress, have discussed the need to ensure that we are achieving the goal of interoperable health IT and the meaningful exchange of information that is a product of truly interoperable systems. Creating a modest yet dedicated revenue source for certifying EHRs would ensure that ONC has adequate testing tools, standards, and implementation guides to assist developers in supporting their customers' needs toward participation in interoperable health information exchange and the delivery of high quality care under new payment models.

The ONC HIT Certification Program provides supporting standards, testing tools, and implementation guides to promote and accelerate the development and adoption of certified health IT. Until now, the HIT Certification Program has largely relied on Recovery Act funds that will expire beginning at the end of FY 2013. Based on the rapid expansion of the health IT marketplace and ONC's increased responsibilities, ONC is proposing a user fee in the FY 2014 CJ that would create a dedicated revenue source to meet the current and future needs of the HIT Certification Program. The proposed user fee would allow ONC to invest additional resources to improve the efficiency and rigor of the certification process for the developers of health IT products.

If approved, the Secretary would be provided to establish a fee structure that would be equitable and reflect differences among products, developers, and type of certification. For example,fees for an electronic prescribing module would be less than fees for a complete EHR system. ONC would provide ample opportunity for public comment and feedback on any proposed user fee structure.

In particular, the CJ identified that the user fee could be used to fund:

- Development of implementation guides and other forms of technical assistance for incorporating standards and specifications into products;
- Development of health IT testing tools that are used by developers, testing laboratories and certification bodies;
- Development of consensus standards, specifications and policies for health IT certification criteria;
- Administration of the ONC Health IT Certification Program and maintenance of the Certified Health IT Product List; or
- Post-market surveillance, field testing and monitoring of certified products to ensure they are meeting applicable performance metrics in the clinical environment.

Please see the Language Analysis (page 8) and Appendix B (page 55) of ONC's Congressional Justification (CJ) for legislative language and a more detailed explanation of the proposed user fee. The CJ can be accessed at http://www.healthit.gov/sites/default/files/fy-2014-onc-cj-040213.pdf

Senator Carper:

Bundled Payments to Post-Acute Providers

1. **Does the administration have the statutory authority to implement the President's proposal for bundled payments to post-acute health care providers?**

Answer: No, we would need statutory authority to implement the FY 2014 President's budget proposal for bundled payments to post-acute care providers.

2. **If not, what statutory authority and language are needed?**

Answer: We would need statutory authority to allow the Secretary to make payment under a bundled payment methodology for post-acute care services in lieu of making payment under current payment systems for each type of post-acute service.

Medigap

3. **Does the administration's proposal for imposing a Medicare Part B premium surcharge for beneficiaries purchasing first-dollar Medigap coverage extend to Medicare beneficiaries with additional coverage from private company retirement plans?**

Answer: No. The proposal generally does not apply to coverage provided by retirement plans of employers or labor organizations. The proposal would, however, apply to beneficiaries who receive a subsidy from a private company retirement plan to separately purchase a standard Medigap plan with a model benefit package that triggered the Part B premium surcharge. The proposal would introduce a Part B premium surcharge for new beneficiaries who purchase Medigap policies with particularly low cost-sharing requirements, effective in 2017. Other Medigap plans that meet minimum cost-sharing requirements would be exempt from the surcharge.

4. **Would the administration expect to see increased savings from this proposal if these private retirement plans were also prohibited from providing first-dollar wraparound coverage?**

Answer: The proposal is expected to generate savings by creating incentives for the selection of Medigap model plans that do not have first dollar or near first dollar coverage of cost sharing over those that do not. The effect of extending such a requirement to private retirement plans would vary depending on the extent of current coverage and cost sharing in those plans

Definition of Full-Time Employee

Many large employers and small businesses have expressed concerns about the Affordable Care Act's definition of a full-time worker as individuals who work for 30 hours per week or more.

5. **In your conversations with businesses, how do most employers define full-time workers in terms of the number of hours worked per week?**

Answer: The definition of full-time employee is prescribed by statute in Section 4980H(c) (4) of the Internal Revenue Code (the Code) of 1986. The Department of Treasury is responsible for regulations implementing Code provisions. In December of 2012, the Department of Treasury released a proposed rule *Shared Responsibility for Employers Regarding Health Coverage*, which can be found here: http://www.irs.gov/pub/newsroom/reg-138006-12.pdf . The regulation discusses, among other things, methods of calculating the 30 hours of services per week for large employers.

Senator Casey:

CHGME

During your appearance before the Senate Finance Committee, I noted my disappointment with the recommendation of just $88 million for the CHGME in the President's budget. Additionally, the Administration's proposes in its budget that CHGME funding should

only support "direct" medical education costs. I believe that this would run counter to the reasons Congress enacted CHGME, and negatively impact the ability of children's hospitals to meet pediatric workforce needs.

CHGME's original authorization provided recipient hospitals with support for both direct (DGME) and indirect (IME) costs of teaching, mirroring the structure of the division of funds available under Medicare. In this way, the program was designed to be consistent with Medicare and promote equity with other teaching hospitals receiving Medicare GME.

Under Medicare, the IME payment adjustment reflects higher patient care costs associated with training residents and is measured by a teaching hospital's teaching intensity, i.e. resident to bed ratio. Eliminating support for indirect costs from CHGME would mean failing to recognize the higher patient care costs of the special services provided at freestanding children's hospitals and the unique training related to those services that occur at these institutions

1. **Why would the Administration propose to create an additional inequity between the CHGME program and Medicare GME, which does recognize indirect costs for training occurring in adult hospitals, including training of pediatric residents in adult hospitals?**

Answer: While the CHGME program has benefited many facilities across the country, we are working within the context of a budget that requires tough choices. A challenging budget environment required a closer examination of how resources are spent. The FY 2014 President's Budget provides $88 million to fund the CHGME payment. This proposed funding level is adequate to support expenses that directly support the residents and faculty, so that training in pediatric care can continue, but does not provide funding for the indirect costs.

2. **Additionally, why would the administration propose to support training for pediatricians and children's health care providers to a lesser degree than it does for training for adult providers by eliminating support for indirect medical education?**

    a. **Doesn't the training of pediatricians and pediatric specialists warrant the same level of commitment as that of practitioners of adult medicine?**

Answer: Different from Medicare's payments to teaching hospitals, the CHGME program operates under annual appropriations. Although the President's Budget does not include funds for CHGME payments to children's teaching hospitals for indirect medical education expenses, it does include funding to these hospitals for direct medical education expenses, which support residents and faculty, so that training in pediatric care can continue.

<u>Medicare in-office ancillary services exception (IOASE)</u>

I wanted to follow up on my question to CMS Acting Administrator Marilyn Tavenner and try and get a more detailed response regarding the Medicare in-office ancillary services exception (IOASE).

3. I respectfully request additional information, specifically the definition of "accountability standards" OMB used to develop this policy and the data OMB relied upon to achieve these savings.

Answer: This proposal allows the Secretary flexibility to determine these standards, which would be done through a rulemaking process. Factors to be considered could include quality, value, efficiency, utilization, and access.

Both the GAO and MedPAC have looked at the Medicare in-office ancillary services exception (IOASE), but neither has actually recommended repealing it. Yet, the President's budget seeks to exclude certain services from the IOASE. The administration's proposal would exclude "radiation therapy, therapy services, and advanced imaging from the in-office ancillary services exception to the prohibition against physician self-referrals (Stark law), except in cases where a practice meets certain accountability standards, as defined by the Secretary" and results in a savings of $6.1 billion over 10 years. I have several questions about this proposed policy.

4. Why did the administration decide to exclude these services from the IOASE?

Answer: The in-office ancillary services exception was intended to allow physicians to self-refer for services to be performed by their group practices for patient convenience. While there are many appropriate uses for this exception, evidence suggests that this exception may have resulted in overutilization and rapid growth of certain services, including advanced imaging. GAO and MedPAC have also found increased utilization of certain services in recent years.

5. When OMB modeled this proposal, how did they define "accountability standards?"

Answer: The term "accountability standards" was not defined; rather, it was expected that the Secretary would have flexibility to determine these standards through rulemaking. Factors to be considered could include quality, value, efficiency, utilization, and access.

6. And lastly, could you please share the analysis and the data used to determine the $6.1 billion savings?

Answer: The estimate of $6 billion over 10 years in savings was developed by the independent CMS Office of the Actuary based on its assumptions about predicted reductions in spending on services and behavioral changes related to the policy.

Medicare Pharmacy Provisions

Secretary Sebelius, I appreciate HHS's proposed goals to reduce healthcare costs and produce a more efficient healthcare system; however, I have concerns with some proposals contained in the FY2014 HHS Budget. In a proposal to "Lower Drug Costs", HHS

proposes excluding authorized generic drugs from the calculation of average manufacture price (AMP) and calculating Medicaid Federal Upper Limits (FULs) based only on generic drug prices. While the goal of this provision may be to decrease Medicaid costs, I believe it may in fact reduce access to prescription drugs and pharmacy services for Medicaid patients, resulting in increased overall healthcare expenditures.

Given that AMP has never been used as a basis for pharmacy reimbursement, and that AMP-based FULs remain in draft form, I'm concerned that the FY2014 budget provisions changing the calculation of FULs are premature. In any given month, over one-third of the draft FULs are below National Average Drug Acquisition Cost (NADAC). This analysis confirms that additional efforts by the Centers for Medicare and Medicaid Services (CMS) are necessary to ensure that pharmacies are not reimbursed below their costs using the reimbursement formula created by the Affordable Care Act.

I urge you to utilize the rulemaking process to implement the Medicaid pharmacy provisions in a manner consistent with congressional intent, rather than pursuing policies that would further cut pharmacy reimbursement.

7. **Why has the Administration proposed this change and what portion of the $8.8 billion in savings from this budget provision is attributed to reduced pharmacy payments?**

Answer: The Medicaid prescription drug proposals in the President's Fiscal Year 2014 budget strengthen the fiscal management of the Medicaid program. If enacted, we estimate the proposals will save money for both the federal and state governments.

The Medicaid Federal Upper Limit (FUL) is used to limit reimbursement for certain multiple source drugs, and is currently calculated based on the weighted average price of all brand-name, authorized generic, and other multiple source generic drugs for each product. This proposal removes brand and authorized generic prices from the FUL calculation. Currently, the inclusion of both brand and authorized generic drugs in the calculation of the FUL unduly inflates the FUL. Removing both categories of drugs ensures that the government remains a prudent purchaser of prescription drugs.

Additionally, the budget includes a proposal to remove authorized generic drugs from brand rebate calculations, to base the rebate only on brand prices. The Medicaid drug rebate program currently includes the prices of authorized generic drugs in a brand drug's rebate calculation, which keeps the rebate artificially low since authorized generics are produced by manufacturers of brand-name drugs, but are priced to compete with generic drugs.

Reimbursement for Medicare Part B Drugs

I note with concern the proposal included in the FY 2014 budget to reduce reimbursement for Medicare part B drugs/biologics to ASP+3%. Reimbursement is already being reduced to ASP+4.3% as a result of sequestration and we have seen numerous reports about the access issues this will create.

8. **Have you determined the impact of this proposal to further reduce the rate on beneficiary access to lifesaving medications? Especially those with chronic conditions and those who live in rural areas?**

Answer: Reducing the Medicare reimbursement level to 103 percent of ASP is not expected to reduce access to medications covered by the proposal. GAO analysis and other evidence indicates that the ASP methodology overpays physicians for many of the expensive drugs they provide.

Senator Enzi:

Home Health Rebasing

Madam Secretary, I am interested in understanding what factors you intend to consider as you implement the home-health rebasing provision in the health care law. The provision allows you to reduce payments to home health providers each year from 2014 through 2017 by up to 3.5 percentage points per year. While this provision was inserted by Congress as a response to concerns that home health providers were "overpaid" by Medicare, a recent analysis by a health economics firm suggests that home health providers in Wyoming and several other states will likely face negative Medicare margins by 2017 if not sooner -- even if CMS were to set the rebasing rate each year at zero.

I'm concerned about the impact that rebasing could have on access for seniors who depend on critical home healthcare services, especially in rural and frontier areas like Wyoming, where the costs of delivering home health care tend to be greater than in non-rural areas.

1. **Can you explain how you intend to implement the rebasing provision?**

Answer: The Affordable Care Act (ACA) requires that, starting in CY 2014, we apply an adjustment to the home health prospective payment amounts to reflect factors such as changes in the number of visits in an episode, the mix of services in an episode, the level of intensity of services, the average cost of providing care per episode, and other relevant factors. Any adjustment must be phased-in over a four year period in equal increments, not to exceed 3.5 percent of the payment amount (or amounts) applicable as of the date of enactment of the ACA.

2. **How will you ensure that, if you implement the rebasing provision, there will not be a disparate impact on rural home health providers?**

Answer: Current law provides for a rural add-on to home health Prospective Payment System payments. This add-on will be maintained through calendar year 2015, after the implementation of rebasing, as the law requires. We will carefully consider the comments of rural and other providers in the rulemaking process this year to ensure we understand the full impact of the

provision, and continue to monitor for unintended consequences of the finalized provisions when they take effect in 2014.

3. Will CMS account for the various other provisions that have reduced Medicare payments for home health providers when considering whether or not to implement the rebasing?

Answer: Yes. The law requires that we estimate 2013 payments. In doing so, we plan to account for past provisions (such as case-mix and coding adjustments) that reduced Medicare payments to home health agencies.

4. How will you ensure that any rebasing is carried out in a fair and transparent manner?

Answer: CMS will publish a proposed rule in early summer outlining a methodology, data, and approach implementing this provision of law. This process will allow for a 60 day public comment period where stakeholders can submit their comments, concerns, and ideas. We also plan to provide the public with a "public use file" that contains critical data used in the proposed rebasing process. The "public use file" will allow the public to replicate our calculations and provide transparency around the Agency's approach to determining the proposed rebasing adjustment.

Chained CPI and Medicare Doc Fix

The President's budget claims $401 billion in mandatory health care savings over ten years. However, the budget also assumes that Congress will pass another Medicare "doc fix", which will cost hundreds of billions of dollars over the ten year window. The President's budget also proposes turning off the Budget Control Act (BCA) sequester and adopting chained CPI for "non-means tested" programs, but these policies are included in the budget as an allowance. Thus, the impact of the proposals is reflected in overall levels of spending and deficits but the budget does not show their effect on mandatory health care spending.

5. Given these proposals and allocations, how can the President claim that his budget includes $400 billion in mandatory health care savings?

Answer: The President's Budget, taken as a whole, presents a policy baseline that both accounts for the cost of a "doc fix," ends sequestration, and reduces the deficit, with $400 billion in identified mandatory health care savings. The Administration supports reforms that strengthen Medicare and Medicaid while preserving the fundamental compact that these programs represent. The Administration believes the country needs to move toward a health care system in which there are better incentives for providers to furnish high-quality care rather than simply providing more care.

Senator Wyden:

Access to Medicare Claims Data

The ACA included a provision that allow "qualified entities" to access Medicare claims data for analytical and academic purposes. The President's FY14 Budget would expand this scope of what qualified entities could use the data for. These entities would also be able to release raw claims data instead of summary reports as they are currently allowed to do.

I appreciate that the President's Budget expands Medicare Data Sharing with so-called "qualified entities," but I still think claims data transparency can go farther. For example, as I understand it, qualified entities would even have the ability to share raw claims data with interested Medicare providers under this provision of the Budget.

1. **Why not take out the middleman? Why limit who has access to raw claims data based on whether or not a provider has a relationship with a "qualified entity?"**

Answer: The Affordable Care Act includes a provision that allows CMS to make Medicare Part A, B, or D claims data available to qualified entities for the purpose of publishing reports evaluating the performance of providers and suppliers. The budget proposal would expand the scope of how qualified entities can use Medicare data beyond simply performance measurement. For example, entities would be allowed to use the data for fraud prevention activities and value-added analysis for physicians. In addition, qualified entities would be able to release raw claims data, instead of simply summary reports, to interested Medicare providers for care coordination and practice improvement.

Qualified entities (QEs) offer a unique mechanism for CMS to share data with providers. Many of the organizations that have been approved as QEs were already doing provider performance measurement, so have established relationships with providers in their region. In many cases, these organizations already share claims data from other payers with providers, offering not only access to the data, but also value-added analytics. Many QEs charge for their value-added analytics; however, this offers an important service to providers, who don't necessarily have the infrastructure to store and analyze raw claims data, which allows them to gather further information on the quality of care they deliver.

We are also considering other mechanisms to give providers access to raw claims data. Currently, CMS is sharing claims data with accountable care organizations across the country. In addition, several other CMS programs such as the Quality Resource Use Reports and the Hospital Value-Based Purchasing program are ensuring providers have access to important quality measure and cost information on how they provide care. Finally, Section 609b of the American Taxpayer Relief Act asks the Secretary to develop a strategy to provide data for timely performance improvement to Medicare providers and CMS is hard at work developing this strategy.

2. **The Center for American Progress has endorsed the legislation Sen. Grassley and I introduced last Congress, and will be introducing again in short order, and has gone further to suggest including Medicaid data as well.**

   Given the widespread interest in making more data available, will you work with me to fully open the Medicare Claims Database?

Answer: CMS is committed to greater data transparency in an effort to transform the health care system to be more data driven and information based. Section 609b of the American Taxpayer Relief Act asks the Secretary to develop a strategy to provide data for timely performance improvement to Medicare providers and CMS is hard at work developing this strategy. We appreciate your commitment to greater data transparency and we are interested in learning more about your proposal.

<u>Wellness Programs</u>

Last week during her nomination hearing, Sen. Portman asked Ms. Tavenner if she would be open and/or interested in exploring the idea of wellness programs for those in the Medicare program. As you know, Sen. Portman and I have introduced the Medicare Better Health Rewards Program, and will be introducing again very soon. Ms. Tavenner indicated that she would be interested in looking at wellness programs – with financial incentives for those who improve or maintain good health – in the Medicare program.

3. **As the other half of our bipartisan duo I'd like to ask: would you also support engaging on this topic and exploring the opportunities that might come as a result of encouraging wellness and prevention for Medicare enrollees?**

Answer: Wellness and prevention for Medicare enrollees is a priority for the Administration and I am happy to work with you on these efforts. As you know, the Affordable Care Act established a new Annual Wellness Visit benefit at no charge to beneficiaries. While this is still a relatively new benefit (beginning in 2011), over 3 million people with Original Medicare obtained an Annual Wellness Visit in 2012 (as well as additional beneficiaries in MA plans). Additionally, CMS has undertaken a range of initiatives to educate providers and beneficiaries about the importance of prevention and Medicare coverage of preventive services including the Annual Wellness Visit.

<u>Expanding the Health Care Workforce</u>

The FY14 Budget includes over $850 million to help expand the healthcare workforce. Priorities for this funding include training for primary care, dental and pediatric health providers, and advanced practice nurses. Of that total, $169 million is dedicated to the current nursing shortage, while $39 million is provided to increase the number of social workers and psychologists in work in rural areas.

I think it is imperative that issue of "healthcare workforce" be discussed in earnest, and I am glad to see that funding for new providers is included in the President's Budget. Having said that, more than 30 million people will have a new insurance card on January 1st that many are looking forward to using. We need to be moving on this now.

4. Has the Administration been engaged in conversations about what can be done now, today to help alleviate the need for additional providers?

Answer: HRSA works with states, academic institutions, professional organizations, and other key stakeholders to address needs for doctors, nurses, and other providers in the health professions workforce. Today, HRSA is supporting several efforts to increase the health workforce, with a particular focus on primary care providers:

- HRSA is funding the expansion of primary care training programs at schools and universities. By 2015 HRSA will have supported the addition of 500 primary care physicians, 600 primary care advanced practice nurses, 600 physician assistants, and 200 more mental/behavioral health providers, into the U.S. health workforce.

- HRSA's Teaching Health Center GME Payments are currently supporting 45 programs and almost 350 physician and dental resident FTEs in primary care. This program has an emphasis on training in community-based settings, including in rural areas and for underserved patient populations. The number of funded residents more than doubled compared to the previous year.

- HRSA is supporting efforts to increase the number of graduate-level social workers and doctoral-trained psychologists who will pursue careers to work with rural, vulnerable and/or underserved patient populations, including military personnel, veterans, and their families.

- HRSA's programs increase the diversity of the health workforce to address needs across the country for culturally competent care. For example, HRSA's Scholarship for Disadvantaged Students program supports the efforts of health professions schools (such as schools of nursing and schools of dentistry) to offer scholarships to financially needy students.

- Health professions students in medical, dental, nurse practitioner, physician assistant, and nurse midwifery programs who intend to practice primary care, are supported by the National Health Service Corps Scholarship Program. At the completion of their training, NHSC Scholars dedicate 2 to 4 years of service at an NHSC-approved site in a high-need HPSA.

- The National Health Service Corps' Students to Service Loan Repayment Program provides financial support to fourth year primary care medical students in exchange for their service in the communities that need them most.

5. Can you comment on the possibility of encouraging more providers to practice at the top of their license?

Answer: The Department has taken and continues to pursue a diverse array of initiatives explicitly focused on full and effective use of the entire health workforce. These activities include training health workers in new and more efficient models of care, investing in tools to support and promote these new care models, changing payment rules to incentivize more effective use of health workers, and enjoining stakeholders to pursue the full range of strategies in their purview to advance full use of the workforce. In addition, the Department has charged its operating divisions to work across units to seek out and synergize efforts in health workforce development. Specifically:

- HRSA is working with the CMS Innovation Center to incorporate workforce innovation across its initiatives in order to build the evidence base for new workforce models that fully and more effectively deploy the entire range of health workers—from specialty physicians to community health workers—and for new payment models that deploy the workforce in the most cost-effective ways.

- HRSA grants have placed a high priority on supporting interprofessional training and team-based models of care, which are the foundation for full and more effective use of the entire health workforce. To that end, in FY 2012 HRSA funded the National Center for Interprofessional Practice and Education, a public-private partnership that is facilitating the transformation of health care workforce by integrating interprofessional practice and education. By aligning and integrating the needs and interests of health workforce training and practice, the National Center aims to find successful ways for our health workforce to work together to make care more safe, efficient, and patient-centered.

- Our cooperative agreements with a number of state-based organizations, such as the National Governors Association and the Association of State and Territorial Health Officials, provide an opportunity to collaborate with our state partners to overcome the barriers to full, effective use of the health workforce. For example, with HRSA support the NGA has developed a policy brief describing regulatory remedies that states are using to remove barriers to full practice potential. Similar briefs for other disciplines may be developed in the future. These cooperative agreements have also supported the development of learning collaboratives where best practices can be shared among states around workforce and other health care issues

- HRSA is also collaborating with the HHS Office of the National Coordinator for Health IT to ensure that our investments in health IT have and will continue to support team-based care, efficient workflows, and using all health workers to the full extent of the scope and training.

Of course physicians need to be trained, but in my state of Oregon, nurse practitioners are considered primary care providers. Medicare however, does not include nurse practitioners as primary care providers.

6. Is this something you would explore as a means of expanding access to patients?

Answer: We recognize the need to invest in the workforce to improve the health care system. New payment reforms, like accountable care organizations and other models to promote coordination can play a role in addressing a shortage of physicians by encouraging a team approach to medicine. By using the skills of other providers, like nurse practitioners and pharmacists, this approach allows physician to more efficiently use their time. In addition, CMS has implemented the Affordable Care Act's 10 percent payment increase for Medicare primary care services provided by primary care practitioners, including nurse practitioners. And the Health Care Innovation Awards are testing ideas to strengthen the primary care workforce.

In 2012, CMS revised the hospital conditions of participation to broaden the concept of the medical staff and allow hospitals the flexibility to include other practitioners as eligible candidates for the medical staff in accordance with state law. Non-physician practitioners are capable of handling many common patient complaints, initial patient work-up and follow-up, patient education and counseling, and other specific aspects of patient care. Physicians, as leaders of these teams due to their more extensive training and expertise, are then able to more fully turn their attention to more complicated patient problems. In this way, non-physician medical staff members allow physicians to more efficiently and effectively manage their time so that these physician leaders can focus on more medically complex patients.

Currently, Medicare provides coverage for those services furnished by nurse practitioners which would be physicians' services if furnished by a physician and which are furnished by a nurse practitioner working in collaboration with a physician only if the nurse practitioner is legally authorized to perform the services by the state in which the services are furnished. The Medicare law would need to be changed to eliminate the requirement that the nurse practitioner work in collaboration with a physician.

CMS has also implemented the Affordable Care Act's Graduate Nurse Education Demonstration to support hospitals for the cost of providing clinical training to advanced practice registered nurse students. Five hospitals were selected, including the Hospital of the University of Pennsylvania, Duke University Hospital, and Memorial-Hermann Texas Medical Center Hospital. Finally, CMS is working closely with our partner agencies across HHS, including the Health Resources and Services Administration (HRSA), to ensure an adequate pipeline of primary care providers is supported.

Senator Menendez:

Exchange Grants

NJ Exchange Grants – As you know, the Governor of New Jersey has decided not to implement a New Jersey health insurance exchange under the Affordable Care Act. As such, New Jersey will have a Federally Facilitated Exchange (FFE) starting next year. Prior to the Governor's decision, the state received nearly $9 million in federal exchange

grants ($1,223,186 in Planning Grants and $7,674,130 in Exchange Establishment Grants).

It has recently been brought to light that the New Jersey Department of Banking and Insurance (DOBI), the state insurance regulator, has only spent $3,400 of the more than $7.6 million in Exchange Establishment Grants received.

1. **What is HHS's intention regarding these unused funds?**

Answer: Funds awarded to states under Section 1311 of the Affordable Care Act must be used for allowable costs and expenses, as requirements are outlined in the terms and conditions of the grant award to each state. States are permitted to request a change in the scope of their Level One Exchange Establishment grants and to continue to pay for allowable expenses under Section 1311 of the Affordable Care Act. If a state does not receive approval for a change in scope from HHS, or fails to draw down funds in a timely manner, funds can be de-obligated and the grant terminated.

2. **Is DOBI going to be allowed to keep these funds, possibly to be used on non-exchange or health related expenses, or will HHS recoup the money and ensure it is used to establish and maintain the New Jersey FFE, as originally intended?**

Answer: Funds awarded to states under Section 1311 of the Affordable Care Act must be used for allowable costs and expenses, as outlined in the terms and conditions of the grant award to each state.

Grant funds are not provided upfront to states. States are reimbursed, or "draw down", federal funds after incurring a permitted expense under the grant. This process protects federal funds and, as a result, HHS does not typically need to recoup grant expenditures. If a state does not receive approval for a change in the scope of the grant from HHS, or fails to draw down funds in a timely manner, funds can be de-obligated and the grant terminated. To clarify, funds that are de-obligated from these grants may not be used by HHS to operate the FFE.

Biologics

Follow-on Biologics – New Jersey is home to some of the world's leading medical researchers, who are working everyday to advance new and innovative biologic therapies to combat disease and illness. In order to ensure New Jersey – and the United States – remains on the forefront of innovation and development of these new therapies, we need to guarantee robust and reliable intellectual property protections.

The budget calls for a reduction in patent protection on these innovative, complex biologic products from the current 12 years down to seven. Such a reduction will severely restrict the ability of researchers to develop and bring to market new biologic therapies.

In your testimony you state that this budget supports "critical investments" in support of scientific innovation.

3. How can that be accurate when proposals such as this explicitly limit the ability to invest in the innovative research necessary to find new biologic therapies?

Answer: The FY 2014 President's Budget would enable FDA to sustain and expand its mission of protecting and promoting the health and well being of the nation including the safety and effectiveness of drugs, biological products, and medical devices. The President's Budget proposes to decrease the period of market exclusivity for brand biological products from twelve years to seven years in order to increase access to biological products, while retaining incentives for research and development for innovation of breakthrough products. The proposal would also clarify the existing statutory prohibition on "evergreening" of brand biological products by making it explicit that only structural changes that result in a clinically significant improvement in safety, purity or potency can qualify an existing biological product for a new term of exclusivity. This proposal does not affect patent protection for biologic or other products.

4. Does including this proposal in the HHS budget indicate the Administration's intent to pursue a similar reduction in patent protection in trade deals, such as the Trans-Pacific Partnership currently being negotiated?

Answer: The Trans-Pacific Partnership initiative aims to enhance trade and investment among partner countries in the Asia Pacific region, boost economic growth, promote innovation, and support the creation and retention of jobs. Participating countries in the Trans-Pacific Partnership have agreed to reinforce and develop existing World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) rights and obligations to ensure an effective and balanced approach to intellectual property rights. The Administration has welcomed diverse stakeholder input in the development of proposals to promote access to innovation and generic medicines. Details of the initiative continue to be developed through ongoing negotiations to develop a comprehensive agreement.

Puerto Rico Physician Supply

During the hearing we discussed the importance of ensuring a robust health care workforce. There was a recent article by the Associated Press (which can be found here) highlighting the growing problem in Puerto Rico of physicians leaving the island, resulting in problems accessing health care. According to this article, the island has seen a 13 percent reduction in the number of doctors practicing in Puerto Rico over the last five years, with the biggest reductions in both primary care and highly-trained sub-specialists. This is adding to the already significant physician shortage on the island and could result in an access crisis for those living there. One of the leading factors in the physician emigration out of Puerto Rico is the substantially lower payments they receive relative to physicians in other parts of the country.

One of the ways to rectify this disparity can be done administratively, through an adjustment to the island's geographic practice cost indices (GPCIs). The GPCIs factor in the variations in the costs of physician work, practice expenses and malpractice insurance when determining a physician's Medicare reimbursements. The GPCIs for Puerto Rico are below those found anywhere else in the country, and substantially lower than those in other territories, such as the U.S. Virgin Islands. It has been recognized by CMS and others that this disparity is largely the result of incomplete, inaccurate or outdated data used to calculate the GPCIs.

5. What steps are HHS and CMS taking to improve Puerto Rico's GPCIs to better account for the costs physicians face on the island?

Answer: Section 1848(e)(1)(A) of the Act requires us to develop separate GPCIs to measure resource cost differences among localities compared to the national average for each of the three fee schedule components (that is, work, practice expense (PE), and malpractice). While generally requiring that the PE and malpractice GPCIs reflect the full relative cost differences, the statute requires that the physician work GPCIs reflect only one-quarter of the relative cost differences compared to the national average.

In recent years, representatives of Puerto Rico have raised numerous concerns about their GPCI values. Puerto Rico has low GPCIs because the data that we use to determine the GPCIs indicates that Puerto Rico has low costs relative to the national average. Nevertheless, CMS has been exploring this issue to determine whether Puerto Rico's costs are being accurately reflected in the GPCI. One factor that is expected to the affect the Puerto Rico GPCI next year is the expiration of the floor on the work GPCI. Currently, the statute required a floor on the work GPCI of 1.0. Puerto Rico has benefitted from that floor.

The expiration on the statutory floor for the work GPCI will result in a decrease in the work GPCI for Puerto Rico which will in turn reduce payment for the work component of physician fee schedule payments. While the malpractice GPCI is used to adjust a relatively small portion of physician fee schedule payments, CMS is actively working with Puerto Rico to ensure we have the latest and most updated data on malpractice premiums in Puerto Rico. Per prior commitments to Resident Commissioner Pierluisi's office, we worked directly with the Puerto Rico Insurance Commissioner and Institute of Statistics to obtain data on malpractice insurance premiums. CMS is also evaluating the suggestion that Puerto Rico experiences higher costs associated with shipping of medical equipment and supplies that should be reflected in the practice expense GPCI.

6. What additional steps are HHS and CMS taking to curtail the erosion of the physician workforce in Puerto Rico and ensure that Medicare beneficiaries on the island have access to the care they need?

Answer: Generally, Medicare pays for medical services adjusted for geographic variation in costs (such as is done with the GPCIs described above). In some limited situations such as the 10 percent bonus for services furnished in health professional shortage areas, the law requires

Medicare to pay more in areas where there is an undersupply of health professionals. The Rural Health Clinic and FQHC programs also pay clinics at reasonable cost subject to a per visit limit in order to maintain access to health care services in areas which may be medically underserved. We certainly encourage Puerto Rico to explore these programs to ensure it is benefitting from them where applicable and we also advise contacting the Health Resources and Services Administration which is specifically charged with ensuring access to medical services and CMS' New York Regional Office for assistance with Medicare and Medicaid issues such as those previously mentioned.

Senator Grassley:

Transparency

Transparency brings about accountability, and accountability will strengthen the credibility of medical research, the marketing of ideas and, ultimately, the practice of medicine. The transparency represented by the Grassley-Kohl Sunshine Law is in patients' best interests. I plan to stay vigilant about how this law is implemented, especially after the delays seen already. The goal of sunshine is straightforward, and CMS needs to make certain the reporting and disclosure are complete and clear.

The recently released OIG Special Fraud Alert underscores the need for transparency and sunshine related to a subset of business entities known as Physician Owned Distributors (PODs). The OIG states that PODs "produce substantial fraud and abuse risk and pose dangers to patient safety." This Special Fraud Alert coupled with the sunshine law and CMS final rule requiring PODs to disclose payments to physicians will help shed light on these types of questionable relationships.

1. **Given the now-heightened scrutiny on PODs, how does CMS plan to enforce sunshine compliance among PODs?**

Answer: CMS published the final rule implementing Section 6002 of the Affordable Care Act on February 8, 2013. In the final rule, CMS required certain Physician Owned Distributors (PODs) to report transfers of value to CMS. To provide additional guidance on the reporting and disclosure requirements for all covered entities of Section 6002, CMS recently launched a dedicated webpage for the National Physician Transparency Program, called Open Payments, at http://go.cms.gov/openpayments. The website includes program details such as fact sheets, frequently asked questions and the teaching hospital list that will be used by applicable manufacturers. CMS is currently creating sub-regulatory guidance regarding which PODs are required to report under the Final Rule for ACA 6002. This guidance will be made publicly available on the webpage, as well as through stakeholder meetings. Additionally, the definition of a POD under Open Payments was drafted with the intent to capture as many PODs as possible while still conforming with the statutory language.

2. Does CMS have a mechanism for identifying PODs and ensuring that they report payments to physicians?

Answer: CMS is not aware of a standard listing or resource that identifies PODs currently in operation. CMS does not maintain this information because PODs do not enroll in the Medicare program. However, we did rely on a recent report by the Senate Finance Committee to estimate the number of PODs. The Senate Finance Committee report identified 20 states with multiple PODs and more than 40 PODs in California. When we extrapolate these estimates to the national level, taking into account the disproportionately higher number in California, we estimate that there are approximately 260 PODs currently in the U.S. We further estimate that there are an additional 160 GPOs, which have some form of physician ownership or investment. CMS is working to identify data sources and analytical approaches which could be used to detect systematic under-reporting by applicable manufacturers and applicable group purchasing organizations. We will evaluate whether such methods can also be used to detect under-reporting on PODs.

3. Is CMS working jointly with HHS OIG on the enforcement of PODs?

Answer: CMS routinely works with the HHS Office of Inspector General on the prevention of fraud, waste and abuse by all provider and supplier types. PODs do not enroll in the Medicare program, rather they purchase, arrange for purchase or negotiate the purchase of a covered drug, device, biological or medical supply for groups of individuals or entities that may be enrolled in the Medicare program. CMS works closely with the OIG on all cases when suspected kickbacks are at issue. Additionally, CMS supports OIG investigations and prosecutions. The Affordable Care Act also expanded CMS' authority to suspend Medicare payment pending the investigation of a credible allegation of fraud. CMS has suspended payments over 100 times in collaboration with law enforcement activity since implementing the authority.

Additionally, CMS has put significant safeguards in place to prevent any bad actors from participating in the program, and getting them out of the program quickly. Since March 2011, CMS approved for enrollment nearly 458,435 Medicare providers and suppliers, including 30,105 DMEPOS suppliers, under these enhanced screening requirements of the Affordable Care Act. Because of revalidation and other proactive initiatives, CMS has deactivated 159,449 enrollments, including 24,880 DMEPOS enrollments, and revoked 14,009 enrollments, including 1,753 DMEPOS enrollments.

Competitive Bidding Program

I have several questions related to the current competitive bidding program.

4. What can you tell me about the statistical evidence regarding cost reductions achieved by round one of competitive bidding?

Answer: According to CMS's analysis of claims from 2010 and 2011, the competitive bidding program has reduced DMEPOS spending by approximately $202.1 million—or 42 percent overall—in the nine Round 1 Rebid areas. The program has significantly reduced payment amounts, with an average price reduction of 35 percent from the fee schedule.

5. Were those savings achieved through reduced product cost or by driving patients out of the program and reducing the overall quality of care provided?

Answer: CMS has closely monitored the results of the competitive bidding program since implementation on January 1, 2011, to ensure that savings goals of the program have been achieved and—more important—to ensure that beneficiary access to appropriate supplies and equipment has not been compromised. To ensure effective monitoring, CMS implemented a real-time claims monitoring system that analyzes the utilization of the nine product categories in all competitive bidding areas. Since one of the goals of the new model is to reduce use of inappropriate items and supplies, the CMS claims monitoring system pays particular attention to potential changes in key secondary indicators such as hospital admissions, emergency room visits, physician visits, and admissions to skilled nursing facilities before and after the implementation of the new payment model. The monitoring system looks at three comparison groups of beneficiaries over time: 1) all Medicare beneficiaries living in one of the nine areas compared to beneficiaries living in a similar geographic area not yet subject to competitive bidding (e.g., Orlando vs. Tampa); 2) beneficiaries in one of the nine areas most likely to use a particular item compared to beneficiaries in a similar geographic area most likely to use the item; and 3) beneficiaries actually using an item living in one of the nine areas compared to beneficiaries actually using an item living in a similar geographic area. Beneficiaries are considered likely to use a competitively bid item based on the presence of particular health conditions (for instance, patients with pulmonary disease are monitored for use of oxygen therapy).

For the first year of the program, the CMS real-time claims monitoring and subsequent follow-up has indicated that beneficiaries' access to necessary and appropriate items and supplies has been preserved. Moreover, the rate of use of hospital services, emergency room visits, physician visits, and skilled nursing facility care has remained consistent with the patterns and trends seen throughout the rest of the country.

CMS's monitoring revealed declines in the use of mail-order diabetes test strips and continuous positive airway pressure (CPAP) supplies in the competitive bidding areas. In response to these declines, CMS initiated three rounds of calls to users of these supplies in the nine competitive areas, two rounds of calls for users of mail-order diabetes test strips and one round of calls to users of CPAP supplies. In each round, CMS staff randomly identified 100 beneficiaries who used the items before the program began but had no claims for the items in 2011. The calls revealed that in virtually every case, the beneficiary reported having more than enough supplies on hand, often multiple months' worth, and therefore did not need to obtain additional supplies when the program began. This would suggest that beneficiaries received excessive replacement supplies before they became medically necessary. CMS concludes that the competitive bidding

program may have curbed inappropriate distribution of these supplies that was occurring prior to implementation.

Examples of CMS real-time claims tracking can be found at the following website http://www.cms.gov/DMEPOSCompetitiveBid/01A3_Monitoring.asp#TopOfPage

6. Could you define what, if any, financial standards were used in determining whether a provider was qualified to bid, or whether a provider is capable of providing equipment at their given capacity level?

Answer: CMS has a robust screening process in place to make sure that all bids are bona fide (in other words, rational and feasible). We first screen the bidders to verify that they meet all requirements (i.e., that they are enrolled and accredited and meet financial standards, applicable licensing requirements, and other bidding requirements). We then screen the bids from qualified bidders using statistical measures to identify any bids that are very low in comparison to other bids. Bids that pass the statistical screen are accepted. We ask bidders that submitted bids that fell below the statistical screening thresholds to submit documentation to prove that their bids are sustainable. Bids that are proven feasible are accepted. Bids that are not proven feasible are rejected and are not used to set prices.
The competitive bidding law and regulations specify that the Centers for Medicare & Medicaid Services (CMS) may not award a competitive bidding program contract to a supplier unless that supplier meets applicable financial standards. Applying financial standards to suppliers is needed to assess the expected quality of suppliers, estimate the total potential capacity of selected suppliers, and ensure that selected suppliers are able to continue to serve market demand for the duration of their contracts.

The Request for Bids specifies the financial information used to evaluate suppliers' financial health. This information includes three financial statements (income statements, balance sheets, and statements of cash flows), relevant portions of tax returns, and a recent Credit Report with a numerical score.

Suppliers that plan to expand their capacity beyond their current levels must submit an expansion plan. CMS evaluates this expansion plan, as well as the hardcopy financial documents submitted by the supplier, and may conduct a more detailed evaluation of the supplier to verify their ability to provide the items and services on day one of the contract period. If a bidder's financial health and expansion plan do not support the suppliers estimated increase in capacity, CMS will adjust the capacity to the supplier's historic level.

7. Does the program hold bidders accountable? Does the program ensure that bidders are qualified to deliver the products?

Answer: CMS carefully scrutinizes bidders on the front-end to ensure that qualified suppliers are selected to participate in the program. There are numerous requirements that bidders must meet in order to participate, including applicable licensure, accreditation, and financial standards.

Supplier capacity statements and expansion plans are carefully evaluated to verify that suppliers will be ready on day one to begin operating at the level reported in their bids. In addition, CMS has a robust screening process in place to make sure that all bids are bona fide (in other words, realistic). CMS also requests additional documentation from suppliers for certain bids if the agency identifies a bid as potentially non-bona fide, and CMS rejects any bids that do not pass this evaluation.

8. **Does the program produce bid rates that are financially unsustainable, may produce undesired results, like decreased access to durable medical equipment and drive small and medium size producers out of the market?**

   I remain very concerned that the answers to these questions, regardless of cost-savings achieved, are not leading to improved beneficiary access.

Answer: CMS has a robust screening process in place to make sure that all bids are bona fide (in other words, rational and feasible). We first screen the bidders to verify that they meet all requirements (i.e., that they are enrolled and accredited and meet financial standards, applicable licensing requirements, and other bidding requirements). We then screen the bids from qualified bidders using statistical measures to identify any bids that are very low in comparison to other bids. Bids that pass the statistical screen are accepted. We ask bidders that submitted bids that fell below the statistical screening thresholds to submit a rationale and documentation to prove that their bids are sustainable. Bids that are proven feasible are accepted. Bids that are not proven feasible are rejected and are not used to set prices. CMS is confident that the Round 2 and national mail-order program single payment amounts provide appropriate payment for the equipment and supplies and related services. All bidders are evaluated to ensure that they meet licensing, financial, and, quality standards, and other program requirements. All bids submitted under the program are screened and evaluated to ensure that they are bona fide. The single payment amounts are calculated based on what qualified suppliers bid.

CMS has implemented a robust monitoring program to track and resolve any issues that might occur with program implementation. The monitoring program includes:

- Local, on-the-ground presence in each competitive bidding area through the CMS regional offices and local ombudsmen;

- A complaint process for beneficiaries, caregivers, providers and suppliers to use for reporting concerns about contract suppliers or other competitive bidding implementation issues;

- Contract supplier quarterly reports identifying the brands of products they furnish;

- Real-time claims analysis to identify utilization trends, monitor health outcomes and beneficiary access, address aberrancies in services, and target potential fraud and abuse;

- A CMS Competitive Acquisition Ombudsman who will respond to complaints and inquiries from beneficiaries and suppliers about the application of the program and will issue an annual Report to Congress;

- Secret shopping; and

- Beneficiary surveys.

To date, the data show that the Round 1 Rebid implementation is going very smoothly with very few inquiries or complaints and no changes to beneficiary health outcomes. We will continue to monitor the program closely as it expands and are prepared to address any issues that may arise.

Finally, CMS has taken specific steps to ensure that small suppliers have the opportunity to be considered for participation in the competitive bidding program. These steps include offering small suppliers the opportunity to form networks, a small supplier target, and not requiring suppliers to submit bids for all product categories. The small supplier target is 30 percent, however we have exceeded that target in all rounds to date - in Round One, 51 percent of contracts were awarded to small suppliers, and for Round Two, 62 percent of suppliers offered contracts were small suppliers.

Neurological Diseases and EMGs:

Patients facing symptoms of Lou Gehrig's disease or muscular dystrophy require a nerve conduction and EMG study for a diagnosis. As you know, CMS reduced the payment for these services in 2013, jeopardizing access to these tests. Dozens of patient groups and physician groups have requested that CMS address these cuts.

9. Will the agency grant a refinement panel to review the appropriateness of these values?

Answer: Section 1848(c) of the Act requires payment for physician work, practice expense, and malpractice be established based on relative resources required to furnish a service. We adopted a refinement panel process for the Physician Fee Schedule to assist us in reviewing the public comments on codes with interim final physician work RVUs for a year and in developing final work values for the subsequent year. We have indicated that refinement panels are designed for situations where there is new clinical information available beyond that considered for the interim valuation that might provide a reason for a change in work values and for which a multi-specialty panel of physicians might provide input that would assist us in making work RVU decisions. At least one request for refinement for these codes was submitted by public commenters. Decisions on which codes will be referred to refinement will be made later this spring. We note that changes to the practice expense, and not physician work, are the largest source of reductions in the interim values for these services.

10. Will the agency consider increased payments for 2014 to mitigate the catastrophic consequences for all patients who depend on physicians to care for complex and often chronic neurologic diseases?

Answer: Payment for a service under the Physician Fee Schedule must, in accordance with the statute, be based on the relative resources required to furnish the service. The revisions to payments for nerve conduction studies (NCS) and electromyography (EMG) are part of our efforts to improve payment accuracy by reviewing the resource assumptions for potentially misvalued codes. The potentially misvalued code initiative was developed in response to concerns raised by both Congress and MedPAC that Medicare was making inappropriate payment for some services. Section 3134 of the Affordable Care Act formally codified the agency's misvalued code initiative in statute. One area of review identified in Section 3134 are services that were originally valued separately that are now frequently billed together. The AMA's Current Procedural Terminology (CPT) Editorial Panel recently created new codes to describe EMG and NCS services, and most of these EMG and NCS codes describe combinations of services that are "frequently billed together." We valued physician work and practice expense for these services on an interim basis subject to public comment. We accepted public comment on these values between November 1 and December 31, 2012, and we will respond to comments when the payment rates are finalized for these codes in the CY 2014 Physician Fee Schedule final rule. We believe we must continue to refine Medicare Payments to more accurately reflect the resources associated with physician services.

11. Almost 5 million people aged 65 and older had Alzheimer's disease in 2010 and this number is expected to triple in the next 40 years. As you know, CMS has systematically underappreciated payments for face-to-face cognitive care that AD patients receive. Consequently, we have a growing shortfall of neurologists and other specialists trained to treat Alzheimer's patients.

Will the agency consider reevaluating payments for cognitive care services to assure that the nation has enough doctors, like neurologists, to care for the growing number of people with Alzheimer's disease?

Answer: CMS is continually seeking to refine and update its physician fee schedule system to establish more accurate payment for physician fee schedule services. In addition to the misvalued code initiative, CMS established payment for transitional care management—specific codes that recognize the care coordination services furnished by physicians and other practitioners following the patient's discharge from a hospital or skilled nursing facility into the community. In addition, CMS is currently evaluating whether to establish separate payment for "complex care coordination codes" created by the American Medical Association's CPT Editorial Panel to care for patients with chronic conditions such as those you ask about as well as how to better recognize advanced primary care services.

Physician Payment Reform

In March, the National Commission on Physician Payment Reform released a proposal for realigning physician payment to enable higher quality care at a lower cost. One of their recommendations for short-term changes was to increase reimbursement rates for Evaluation and Management (E&M) care for all physicians. The report makes clear that large gap in physician payments isn't between specialists and primary care, but, rather, between under-reimbursed E&M care versus with well compensated procedures.

12. Do you agree that efforts to boost E&M rates should focus on both primary care as well as cognitive specialists like neurologists, rheumatologists, and psychiatrists, who bill E/M codes as a majority of their practice?

Answer: In 2011, CMS requested public comment on whether 91 evaluation and management (E/M) codes should be reviewed under our misvalued code initiative. While a significant number of commenters generally agreed that health care delivery has changed, that chronic disease management has led to increases in physician time and effort, and that primary care physicians provide valuable services to Medicare beneficiaries, the commenters were against reviewing payment for all E/M services. They indicated that the resource-based relative value system is not the appropriate system to account for changes in health care delivery models. Commenters requested that CMS not review E/M codes because the current E/M codes, as written, do not correspond to the work associated with patient-centered care management. The commenters urged CMS to consider implementing separate codes and payment for care management services.

In response to our CY 2012 discussion of care coordination and interest in re-examining the E/M codes to reflect chronic disease management, the American Medical Association (AMA) and the American Academy of Family Practitioners created workgroups to address primary care services. The AMA created the Care Coordination CPT Workgroup (C3W) to produce recommendations for transitional care management (TCM) services and complex chronic care coordination services. Partly based on the recommendations of the C3W and other physician groups, CMS established separate payment for TCM services for CY 2013 to pay physicians explicitly for care coordination for beneficiaries who are transitioning from a hospital or skilled nursing facility stay to the community. In the final rule, we indicated that we adopted the new CPT TCM codes as one step in the broader CMS multi-year strategy to recognize and support primary care and care management. In the CY 2013 PFS rulemaking, we also solicited comment on targeting primary care management payments to advanced primary care practices. We received many comments, especially on the criteria and processes that should be used to identify such practices. In addition, CMS is further considering whether and how to pay for the new CPT codes created for complex care coordination.

Additional Development Request (ADR) Process

Regarding the Additional Development Request (ADR) process, I have heard from providers who have experienced denials by CGS simply due to lack of a proper tracking

mechanism of medical records, which have resulted in delay of procedures and duplicative work.

13. Is there the fiscal intermediary, who is charged with managing the ADR process, to take responsibility on to have their processes working properly as well as having medical reviewers that are familiar with hospice regulations?

Answer: CMS has four home health and hospice Medicare Administrative Contractors (MACs), previously known as Carriers and Fiscal Intermediaries, that are responsible for managing the overall Medicare ADR process for these provider types. CMS oversees and monitors the MACs ADR processes to ensure they adhere to CMS' guidance. The medical reviewers at the MACs include clinicians who are familiar with Medicare policies, including hospice regulations. The medical review staff is under the supervision of a Medical Director.

14. I have heard from physicians of concerns over the efficiency of a fiscal intermediary involved in the Additional Development Request (ADR) process. I have been told that providers had experienced denials by a Celerian Group Company (CGS), a fiscal intermediary, simply due to lack of a proper tracking mechanism of medical records, which has resulted in delay of procedures and duplicative work.

I would like to know that whether it is CMS's intent that there ought to be a fiscal intermediary who is charged with managing the ADR process, and if so, should such intermediaries take responsibility to have the processes working properly as well as having medical reviewers that are familiar with hospice regulations?

Answer: While CMS acknowledges that there may be intermittent issues, overall, the MACs are performing well with the ADR process. For example, in January 2013, CGS reported a problem with a widespread hospice edit, once the error was discovered they immediately discontinued the edit and released the held claims without further review.

At this time, CMS does not plan to have a single MAC to perform the ADR process. However, CMS has begun preliminary discussions with the four home health and hospice MACs to establish a workgroup to develop consistent medical review processes that facilitate the education of home health and hospice providers about Medicare policies while protecting the Trust Fund. CMS established a similar workgroup with our Durable Medical Equipment MACs that has proven effective in improving consistency of review and better provider education strategies.

Medicare Pharmacy Reimbursement

15. What is the status of Medicaid pharmacy reimbursement changes that were made in Deficit Reduction Act 2005, as well as the Affordable Care Act of 2010?

Answer: *Deficit Reduction Act of 2005*: Following litigation by the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA), a preliminary injunction (PI) was issued in December 2007 by the U.S. District Court for the District of Columbia, halting the implementation of the Federal upper limits (FUL) as calculated under the Deficit Reduction Act of 2005 (DRA). The PI also enjoined CMS from disclosing average manufacturer price (AMP) data to individuals or entities, including states or their representatives. Therefore, neither AMPs nor FULs, as calculated under the DRA, were posted on the CMS' website after the issuance of the injunction in December 2007.

In July 2008, in accordance with the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), CMS published the FULs until September 30, 2009, using the methodology at 42 CFR 447.332, as in effect on December 31, 2006.

In November 2010, CMS issued a final rule which withdrew regulations governing the AMP-based FULs promulgated pursuant to the DRA. Shortly thereafter, the Court issued an order dismissing the case against CMS, which cleared the way for the agency to proceed with implementing FULs under the Affordable Care Act.

The Affordable Care Act of 2010: Effective October 1, 2010, Section 1927(e)(5) of the Social Security Act, revised by Section 2503(a) of the Affordable Care Act, requires that the Secretary calculate a FUL as no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly AMP for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis. The Affordable Care Act further specified that the Secretary implement a smoothing process for AMP prices and that the amendments "shall take effect ... without regard to whether or not final regulations to carry out such amendments have been promulgated by such date...".

In order to facilitate this change, in September 2011, CMS began to issue draft AMP-based FUL reimbursement files for multiple source drugs. The files included the draft methodology used to calculate the FULs, and were based on the most recently reported monthly AMP and AMP unit data. In response to comments received, CMS subsequently began publishing draft FULs calculated using a FUL-smoothing process to minimize month-to-month variation in the draft FULs. At this time, CMS continues to publish the draft monthly AMP-based FULs in addition to the draft "smoothed" FULs files.

16. It has been 8 years almost since the initial changes were made and it is not clear to me that the changes have gone into effect.

How are you assessing or assuring that Medicaid patients will have access to pharmacies through adequate reimbursement?

Answer: With the submission of state plan amendments (SPAs), states must assure CMS that they are in compliance with Section 1902(a)(30)(A) of the Social Security Act which requires that payment for Medicaid services is consistent with efficiency, economy, and quality of care

and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population. CMS works with states to understand how they evaluate access to services and if necessary work with them to develop monitoring tools before approving an SPA to assure continued compliance with Section 1902(a)(30(A) requirements.

17. Do you anticipate making retail survey price information in the aggregate available?

Answer: Yes, we are currently making draft retail price survey information publically available. We currently have draft retail price survey information on our website at http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html.

Diabetic Testing Supplies

Many Medicare beneficiaries and pharmacies from Iowa are concerned that they won't get the diabetic testing supplies that they need to properly test their glucose levels. This may be happening because CMS may have set the single payment amount for these supplies significantly below the current fee schedule amount.

18. Are you concerned about the inability of patients to properly test and that higher Medicare costs will happen as a result?

Answer: CMS is confident that the national mail-order program single payment amounts provide appropriate payment for diabetic testing supplies. All bidders are evaluated to ensure that they meet applicable state licensure requirements, financial standards, quality standards and accreditation requirements, and other program requirements. All bids submitted under the program are screened and evaluated to ensure that they are bona fide. The single payment amounts are calculated based on what qualified suppliers bid.

In regards to diabetic testing supplies sold in a retail pharmacy, CMS was required, by statute, to set payment rates for these items equal to the payment rates for the same items provided through mail-order. CMS does not believe that this statutorily mandated change in payment will impact the ability of pharmacies to offer diabetic test strips to Medicare beneficiaries. We also note that retail pharmacies, unlike national mail order pharmacies, do not have to bill Medicare on an assignment-related basis and therefore can charge customers more than the Medicare-approved amount for diabetic test strips (which is commonly referred to as balance billing). CMS will be closely monitoring access to necessary diabetic supplies following implementation of the new payment amounts.

Diagnostic Radiopharmaceuticals:

Regarding the National Plan to Address Alzheimer's disease, CMS appears to be unwilling to pay for a diagnostic technology, which FDA approved almost a year ago that can identify whether a Medicare beneficiary may have Alzheimer's even though the Alzheimer's Association and Society of Nuclear Medicine and Molecular Imaging recommends coverage.

19. What is CMS's position on covering diagnostic radiopharmaceuticals that are used in conjunction with Positron Emission Tomography?

Answer: CMS' position on covering radiopharmaceuticals used in conjunction with positron emission tomography (PET) have been determined by applicable sections of the Social Security Act, Title 18.

Current CMS decisions about coverage for such radiopharmaceuticals, which are available for review within Section 220.6 of the Medicare National Coverage Determinations Manual, Chapter 1, Part 4, can be summarized by medical indication and radiopharmaceutical as shown below:

- (Subsection 220.6.1): for non-invasive PET imaging of the perfusion of the heart for the diagnosis and management of patients with known or suspected coronary artery disease using either FDA-approved radiopharmaceutical rubidium-82 or nitrogen-13 ammonia.

- (Subsection 220.6.8): for selecting candidates with compromised ventricular function to determine appropriateness for revascularization using fluorine-18 fluorodeoxyglucose (FDG) PET.

- (Subsection 220.6.9): for presurgical evaluation with FDG PET for the purpose of localizing a focus of refractory seizure activity.

- (Subsection 220.6.13): for FDG PET scans for either the differential diagnosis of frontotemporal dementia (FTD) or Alzheimer's disease (AD) under specific requirements; OR, for use in a CMS-approved practical clinical trial focused on the utility of FDG PET in the diagnosis or treatment of dementing neurodegenerative diseases.

- (Subsection 220.6.17): for FDG PET for oncologic indications.

- (Subsection 220.6.19): for PET using fluorine-18 NaF to identify bone metastases of cancer.

Also, a recent CMS decision (CAG-00065R2, March 2013, publicly available through the Medicare National Coverage Database) allows for local coverage of FDA-approved PET radiopharmaceuticals not mentioned above (see below for the excerpt from the NCD):

"The Centers for Medicare & Medicaid Services (CMS) has determined that, unless there is a specific national coverage determination, local Medicare Administrative Contractors (MACs) may determine coverage within their respective jurisdictions for positron emission tomography (PET) using radiopharmaceuticals for their Food and Drug Administration (FDA) approved labeled indications for oncologic imaging."

"The effect of this decision is to remove the national noncoverage for FDA approved labeled oncologic uses of radiopharmaceuticals that are not more specifically determined nationally. Thus this decision does not change coverage for any use of PET using radiopharmaceuticals FDG (2-deoxy-2-[F-18] fluoro-D-Glucose (fluorodeoxyglucose)), NaF-18 (fluorine-18 labeled sodium fluoride), ammonia N-13, or rubidium-82 (Rb-82). This decision does not prevent CMS from determining national coverage for any uses of any radiopharmaceuticals in the future, and if such determinations are made, a future determination would supersede local contractor determination."

Additionally, CMS has two open National Coverage Analyses (NCAs) on PET:

- Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease (proposed decision memorandum due July 9)

- Positron Emission Tomography (FDG) for Solid Tumors (proposed decision memorandum released March 13, final decision is due June 11)

Both NCAs are currently under deliberation. The public comments and proposed decision are posted at http://www.cms.gov/medicare-coverage-database/indexes/nca-open-and-closed-index.aspx.

Breast Cancer

Although we continue to make strides in the detection of breast cancer, it still remains the most common cause of cancer among women of all races. Recent technology advances in the field of mammography, breast tomosynthesis, provide three-dimensional breast images for radiologist to review which results in significantly fewer women needing to be recalled for additional diagnostic work-up after their screening mammography. We are fortunate to have breast tomosynthesis in our state and women are benefiting from access to this advanced mammography service. More women, including Medicare age women, however, need to have access to breast tomosynthesis. This advanced mammography technology is being reviewed by CMS. This improved mammography needs to be available to all women and appropriately reimbursed to ensure access.

20. While I understand it might be too soon for your final assessment, I would like to know your time frame for your decision and want to be kept informed of the status of your deliberations.

Answer: Breast tomosynthesis is a new technology that produces direct 3-D digital images, and falls within the scope of the screening mammography benefit under the Medicare program. CMS is in the process of evaluating payment for this digital mammography service. We will be happy to keep you apprised of any actions taken on this topic.

Chronic Wounds

I have a concern raised by an Iowa company I would like to bring to your attention. The company has created a medical device for the treatment of hard to heal wounds. Hard to heal wounds, like diabetic ulcers, are prevalent and the estimated cost to treat them is quite expensive. The wound treatment device has been assigned a non-payment code by the Centers for Medicare & Medicaid Services (CMS). As most of the patients with these types of wounds are elderly and/or lack financial resources, this effectively means that the device will never be widely adopted in the medical community because of the inability to be reimbursed for treatment.

With millions of people suffering with chronic wounds in the U.S. each year, these wounds are of special interest to the healthcare community due to their associated costs of care, chronic nature, and detrimental effects on patient quality of life. Diabetic ulcers are the most common cause of foot and leg amputation. There are at least 25 million people with diabetes in the U.S., and approximately 800,000 new cases are diagnosed each year.

21. I would request that CMS review the current code, EO446, from "Topical Oxygen delivery system, not otherwise specified" and consider if the code "Continuous Diffusion of Oxygen, Portable" is more appropriate.

This would allow the company to negotiate directly with the regional CMS administrators for reimbursement on a case by case basis, and would allow the development of clinical data that could lead to widespread adoption of this new, more effective and cheaper hard to heal wound care technology.

Answer: CMS shares your concern regarding the health impact of chronic wounds in the Medicare beneficiary population. We are aware that there are different types of devices which deliver topical oxygen to wounds. Regardless of how the oxygen is provided (intermittently or continuously, under pressurized or non-pressurized conditions, and/or with high or low flow rates), these delivery devices all administer oxygen topically. Topical oxygen is not covered under Medicare (see chapter 1, part 1, section 20.29 of the NCD manual). Changing the code description of this device does not change the applicability of the NCD that non-covers topical oxygen.

We have met with multiple companies that manufacture topical oxygen devices to discuss the types of evidence we review. We also continue to discuss with these manufactures ways they may want to develop quality evidence to support their products. To date, we have not received any additional evidence to support their claims. We continue to engage with these companies

and others that seek information and guidance on obtaining Medicare coverage in an effort to provide the most appropriate therapies for beneficiaries with chronic wounds.

American Health Benefit Exchanges

On March 1, the President formally ordered all government agencies to make across-the-board cuts worth $1.2 trillion over a ten year period. I have written you previously on the unlimited money flowing from your agency to establish American Health Benefit Exchanges. These grants allow HHS unrestricted access to taxpayer dollars with little to no oversight of how taxpayer dollars are being spent. HHS also provides no substantive guidance to State on how these grant dollars should be used.

To date, HHS has awarded more than $1 billion to 33 states for exchange planning and establishment. Senator Hatch and I recently send you a letter asking you a series of questions regarding how HHS will be treating these grants during sequestration.

22. Do you think we can get a response from you by May 1?

Answer: My senior leaders are working on a response and we will send my response letter in the near future.

23. Do you think it is reasonable to trim back the unlimited taxpayer dollars for these grants during sequestration?

Answer: As required by Congress, funding for grants made under authority provided to the Department in Section 1311 of the Affordable Care Act is subject to sequestration. Effective March 1, 2013, all new grants to states to establish Marketplaces have been reduced, consistent with OMB guidance for indefinite appropriations.

Senator Cardin:

Identifying and Coordinating Minority Health Research Funding at NIH

Thank you for your commitment to eliminating health disparities. April is National Minority Health Month and I see that the various Offices at HHS are working to increase awareness of the need for health equity.

I have a particular interest in the newest Institute at NIH, the National institute on Minority Health and Health Disparities, headed by Dr. John Ruffin. I visited with the staff of NIMHD last year and was delighted to see the work they are doing there and to learn about the various research projects they are funding across the country.

The law gives the Director of the Institute the "responsibility of coordinating all research

and activities conducted or supported by the National Institutes of Health on minority health and health disparities." It is his job to "plan, coordinate, review and evaluate research and other activities conducted or supported by the Institutes and Centers of the National Institutes of Health."

1. **Could you tell me how much research funding is dedicated to health disparities research throughout NIH?**

Answer: In FY 2012, $2,740 million in research funding was dedicated to health disparities research throughout NIH.

2. **Can HHS provide an accounting of where and how the research dollars are spent on health disparities research?**

Answer: In FY 2012, the $2,740 million in research dollars was spent on health disparities research conducted by each Institute and Center (IC) at NIH. Please see attached chart detailing the amount each IC spent on health disparities research in FY 2012.

NIH Health Disparities Budget - Total

Institute/Center/Office	FY 2012 Actual
FIC	$ 36,829
NCATS	$8,372,032
NCCAM	$20,773,368
CI	$266,228,338
NEI	$44,385,749
NHGRI	$22,363,873
NHLBI	$354,128,700
NIA	$118,751,373
NIAAA	$77,729,080
NIAID	$252,226,931
NIAMS	$32,649,343
NIBIB	$11,462,099
NICHD	$196,460,379
NIDA	$167,478,380
NIDCD	$42,115,166
NIDCR	$41,808,748
NIDDK	$231,337,536
NIEHS	$82,364,268
NIGMS	$241,584,478
NIMH	$124,684,731
NIMHD	$253,132,361
NINDS	$58,723,237

NINR	$46,765,794
NLM	$5,119,052
OD	$18,454,801
RMAP (Common Fund)	$20,950,626
TOTAL	**$2,740,087,272**

The *NIH Health Disparities Strategic Plan and Budget* is a comprehensive document, which sets the overarching principles for the NIH health disparities agenda. The ongoing and planned projects of the ICs align with the *Strategic Plan* which is structured upon a foundation comprised of four overarching goals, each encompassing specific areas of importance within the individual ICs' health disparities strategic plans: (1) Research; (2) Research Capacity; (3) Community Outreach, Information Dissemination, and Public Health Education; and (4) Integration of Research, Research Capacity Building, and Outreach.

3. **Of the amount of research dollars dedicated to health disparities research at NIH, how much of that research budget does NIMHD receive?**

    a. **Does HHS find this adequate considering NIMHD's mission?**

Answer: In FY 2012, of the amount of research dollars dedicated to health disparities research at NIH, NIMHD received $253,132,361. HHS considers this level adequate.

4. **Senator Kennedy's law, the Minority Health and Health Disparities Research and Education Act of 2000, (PL 106-525) provides for administrative support for NIMHD. Specifically, Section 485 of the law says that "The Secretary, acting through the Director of the National Institutes of Health, shall provide administrative support and support services to the Director of the Center (now Institute) and shall ensure that such support takes maximum advantage of existing administrative structures at the agencies of the National Institutes of Health."**

    What additional resources have you provided to NIMHD to carry out its congressionally-mandated responsibilities to "plan, coordinate, review and evaluate research and other activities conducted or supported by the Institutes and Centers of the National Institutes of Health?"

Answer: The resources for administrative support at NIMHD are primarily in the Resource Management and Support budget mechanism. The level is estimated at $15.5 million in FY 2014.

<u>Therapy Caps and the In-Office Ancillary Exception</u>

I want to thank you for looking for ways to make Medicare a more efficient program. Your FY2014 budget includes a proposal to eliminate certain services, including therapy

services, from the in-office ancillary care exemption of the Medicare ban on physician self-referral. The Administration's proposal is estimated to save more than $6 billion over ten years. In general, I support efforts to weed out inappropriate or unnecessary expenditures before we look to make cuts that affect access to care.

5. Do you believe the savings from this proposal could be used to address areas where real reform is needed, such as the Medicare outpatient therapy caps, which have been in law since 1998?

Answer: The in-office ancillary services exception was intended to allow physicians to self-refer for services to be performed by their group practices for patient convenience. While there are many appropriate uses for this exception, evidence suggests that this exception may have resulted in overutilization and rapid growth of certain services over time. Effective calendar year 2015, this proposal would seek to encourage more appropriate use of select services by amending the in-office ancillary services exception to prohibit certain referrals for radiation therapy, therapy services, and advanced imaging, except in cases where a practice meets certain accountability standards, as defined by the Secretary.

The President's FY 2014 budget proposes targeted reforms to Medicare and Medicaid that are projected to save $393.2 billion over the next decade. These reforms will strengthen the long-term sustainability of Medicare and Medicaid and increase the efficiency of the programs, while continuing to provide essential and appropriate care for the elderly, children, low-income families, and people with disabilities." The President's FY 2014 budget does not contain a proposal to eliminate or revise Medicare outpatient therapy caps. However, we have been undertaking data collection and analysis that will inform potential alternative approaches to Medicare payment of outpatient therapy services.

Senator Isakson

Productivity Adjustments

The Patient Protection and Affordable Care Act reduces Medicare spending by $750 billion over the next 10 years to pay for new health care programs. One of the largest of the law's Medicare cuts is a "productivity adjustment" that reduces the annual inflation updates to provider reimbursements. These productivity adjustments will have a compounding effect over time, and when the law was passed, the CMS Office of the Actuary projected that they would cause about 15 percent of hospitals, skilled nursing facilities, hospices, and other Part A providers to become unprofitable within the next 10 years. I am concerned that this may have an especially severe impact on rural areas, where providers are less able to shift costs to patients with private insurance. Already this year, two rural hospitals in my state have been forced to close their doors and have cited reimbursement cuts as a major factor. Despite these concerns, the President's budget proposes to double down on this policy by reducing inflation updates for post-acute care providers by an additional 1.1 percent each year for the next decade.

1. **Have you asked the Office of the Actuary to estimate how many additional facilities would be forced to close down or operate at a loss if this proposal were enacted?**

Answer: We are carefully monitoring access to services, and to date, access to services remains strong. Providers will benefit from the insurance coverage expansions in the Affordable Care Act, as this will add new sources of revenues for most health care providers. Furthermore, a number of provisions in the Affordable Care Act are designed to strengthen the health care workforce, such as Medicare payment bonuses for primary care providers and providers in underserved areas and investments in health professional training programs to increase supply. We will continue to carefully monitor access to ensure our policies continue to lower costs while maintaining access to quality services.

MedPAC reports that Medicare payment significantly exceeds the costs of care in post-acute settings. They also report that post-acute providers have historically had high Medicare profit margins. This proposal would gradually realign payments with costs through adjustments to payment rate updates.

Transitional Reinsurance Programs

Section 1341 of the Patient Protection and Affordable Care Act establishes a transitional reinsurance program intended to stabilize premiums for coverage in the individual market from 2014 to 2016. The Act requires $20 billion to be collected from health insurance issuers and group health plans, including self-insured employers, over the three-year period. HHS has proposed a national per capita fee in 2014 of $63 per covered life, including employees, dependents, early retirees, and COBRA eligible individuals. An additional $5 billion will be collected by the U.S. Department of Treasury. While the statute does not specify the purpose of this additional $5 billion, it was indicated in the December 1, 2012, proposed Notice of Benefit and Payment Parameters that this money is intended to pay for expenditures under the Early Retiree Reinsurance Program. I am concerned about impact of this program on employer-sponsored coverage. I understand HHS has taken the position that PPACA's coverage expansion will reduce costs for employer plans, but a 2010 study found that the Massachusetts health reform plan actually increased premiums for employer-sponsored health plans by an average of about 6 percent.[2]

1. **Have you performed a cost-benefit analysis of how the $63 reinsurance fee will impact employer-sponsored coverage, particularly with respect to coverage of dependents and early retirees?**

Answer: The Affordable Care Act directs that a transitional reinsurance program be established to help stabilize premiums for coverage in the individual market from 2014 through 2016. The

[2] John F. Cogan, R. Glenn Hubbard, and Daniel Kessler, "The Effect of Massachusetts' Health Reform on Employer-Sponsored Insurance Premiums," *Forum for Health Economics and Policy,* 2010. Accessed through http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3251220/.

reinsurance program is designed to alleviate the need for issuers to build into premiums the risk of enrolling individuals with significant unmet medical needs. The program is expected to reduce premiums in the individual market by between 10 to 15 percent in 2014.
To assist with the development of the payment parameters used for reinsurance, HHS developed a model similar to existing national models such as those used by the Congressional Budget Office and Office of the Actuary. The policy resulting from the model aims to maximize the range of health insurance issuers and self-insured group health plans contributing to the reinsurance pool, lowering the cost per enrollee to the extent possible and as permitted by the law. Both the reinsurance program and market reforms such as guaranteed issue should lead to fewer unreimbursed health costs, lowering the costs for issuers and group health plans.

2. If the exchanges are delayed, does HHS intend to delay the collection of this fee?

Answer: Open enrollment will begin October 1, 2013. There is no plan to delay the fee.

Senator Cornyn

1. When was the Department of Health and Human Services (HHS) required to submit its budget proposal to the Office of Management and Budget?

a. Is this similar to the timeline for previous years?

Answer: OMB Circular A-11 specifies when agencies are to submit budget proposals to the Office of Management and Budget (OMB). The initial budget submissions were due to OMB on September 10, 2012, which is consistent with previous years. The FY 2014 guidance can be found online at the following web address:
http://www.whitehouse.gov/sites/default/files/omb/assets/a11_current_year/s25.pdf

PPACA Implementation

In its most recent budget, the Administration requested increased discretionary spending totaling $5.4 billion for next year to implement the law. I assume the Administration did not take into account these additional funding requests when praising the cost savings of PPACA.

2. What has changed over the last few years that require this amount of additional spending?

Answer: In the FY 2014 President's Budget, the discretionary request for implementing the Marketplaces is $1.5 billion in new budget authority at CMS. HHS cost estimates have not increased since the enactment of the Affordable Care Act. To the contrary, HHS has continued to look for efficiencies and ways to reduce overall spending.

3. Would you agree that the bill will cost more than you previously anticipated?

Answer: No. At the time of enactment, CBO estimated ACA administrative costs to HHS of $5 to $10 billion over 10 years, yet the Implementation Fund appropriated in the law included only $1 billion to be shared by HHS and other agencies. HHS is working diligently to implement the Affordable Care Act in a timely and efficient manner.

Premium Costs

A recent article published in Contingencies, a magazine of the American Academy of Actuaries, found that premiums for individuals in the non-group market aged 21 to 29 who are not eligible for premium assistance will increase by 42 percent. For those aged 30 to 39, premiums are expected to increase by 31 percent. Administration officials have noted that the PPACA allows individuals under 30 to purchase a catastrophic plan option. However, the actuaries are predicting large increases for those over 30 and not eligible to purchase catastrophic plan options. In addition, Administration officials often point to the fact that the premium tax credits will offset these premium increases. However, actuaries note that adults up to 44 with incomes above 300 percent of the FPL (approximately $33,510) will see premium increases, even taking into account premium assistance. For those below 30, individuals at about 225 percent of FPL (approximately $25,000) can expect to see premium increases, even after taking into account premium assistance.

4. Do you believe that premiums will rise as a result of the PPACA? Are you concerned about these premium increases?

Answer: No. The individual and small group markets – the markets that much of the Affordable Care Act is designed to improve in particular are broken. People are currently locked out of these markets because of their pre-existing conditions, or if they are able to buy insurance, they may find out their coverage will not extend to the care they need when they get sick. Young women who currently pay for their own insurance plan may discover that, simply on account of their gender, they are charged 50 percent more than young men are for the same plan. This fall, people are going to be able to buy comprehensive insurance without discrimination based on gender or pre-existing conditions.

The Marketplace will increase competition between issuers on the individual market. CBO projects a 7 percent to 10 percent decrease in premiums among comparable plans. Consumers will be able to compare benefits, cost-sharing and premiums across plans and issues will no longer be able to compete on risk selection or medical underwriting, but will compete on price and the quality of coverage they offer.

Additionally, many low- and middle-income individuals and families will qualify for premium tax credits to help them buy insurance. In fact, the Congressional Budget Office estimates that 86% of those purchasing coverage in the Marketplace will be eligible for tax credits.

Also, young adults and certain other people for whom coverage would otherwise be unaffordable may enroll in catastrophic plans, which have lower premiums, protect against high out-of-pocket costs, and cover recommended preventive services without cost sharing. Young people under the age of 26 are also generally allowed to stay on their parents' insurance, helping make insurance more affordable for that group.
There are also many provisions in the law to slow health care cost growth and create competition in the insurance marketplace. For example, the reinsurance and risk adjustment programs will help stabilize premiums. In addition, the medical loss ratio provision (or 80/20 rule) requires issuers to spend at least 80% of premiums on health benefit costs and qualify improvement activities.

Posting PPACA Taxes and Mandates

5. Would HHS have a problem publishing these PPACA taxes and mandates on a website so that the public is aware of the various fees and taxes that must be paid by health insurers?

Answer: The Department of Treasury is responsible for administration of the individual shared responsibility and employer shared responsibility provisions. Throughout the implementation of the Affordable Care Act, HHS exercised flexibility where available to minimize fees on issuers while maintaining sufficient funding to administer the Marketplaces. The Affordable Care Act includes premium stabilization programs that include reinsurance, risk corridors, and risk adjustment that will help to mitigate selection issues and ensure a robust offering of plans in the Marketplace. In regulation, we have implemented both of these programs and specified collections for the administration of such programs in 2014. Details can be found in final HHS Notice of Benefit and Payment Parameters for 2014, published on Monday March 11, 2013 (78 FR 15410).

IPAB

The health reform law specifically states that the Independent Payment Advisory Board's (IPAB's) recommendations may not:

- **Raise revenues;**
- **Raise Medicare beneficiary premiums;**
- **Increase beneficiary cost-sharing (including deductibles, coinsurance, and copayments), or;**
- **Modify eligibility criteria.**

6. What types of proposals do you believe the IPAB could propose?

Answer: The Independent Payment Advisory Board (IPAB) builds on the commitment we have made to our seniors' health. The Affordable Care Act provides for consultation between the President and Congressional leadership in appointing members of the Board, and appointments are subject to the advice and consent of the Senate. The Board's primary responsibility will be to

recommend proposals to reduce the growth in Medicare spending, while taking into account opportunities to improve the health care delivery system, health outcomes, and beneficiary access, among other considerations. For example, the Board could recommend approaches that would build on initiatives such as reducing medical errors, strengthening prevention and improving care coordination, or targeting waste and fraud.

The health reform law also specifically prohibits the IPAB from making recommendations that would "ration health care" or "otherwise restrict benefits."

7. Would you agree that provider payment rates can be cut so low that this ultimately leads to rationing of care?

Answer: The law contains important limitations on what the Board can recommend. The statute is very clear: the IPAB cannot make recommendations that ration care, raise beneficiary premiums or cost sharing, reduce benefits, or change eligibility for Medicare. The IPAB cannot eliminate benefits or decide what care Medicare beneficiaries are entitled to receive. Considering the requirements and limitations on recommendations from the Board, we expect it will focus on ways to find efficiencies in the payment systems and align provider incentives to drive down costs without affecting our seniors' access to the care and treatment they need. Additionally, Congress will have the opportunity to review the Board's recommendations and make changes as it deems appropriate.

Premium Subsidies

Last year, the President's budget estimated that premium subsidies under the health law would cost $478 billion between 2014 and 2021. This year, the estimate is up 27 percent to $606 billion.

8. What has changed between now and then that has driven the costs up this much? Do you expect the cost of these subsidies to continue to rise?

Answer: The Department of Treasury estimates the cost of the premium tax credit program, but our understanding is that the primary factor for increasing costs is the impact of the Supreme Court decision that resulted in some states not being expected to implement the Medicaid expansion. In non-expansion states, some individuals who otherwise would have been enrolled in Medicaid will now receive coverage through Marketplaces and will be eligible for premium tax credits. CBO estimates that 3 million individuals may fall into this category. Medicaid spending is also projected to experience an associated decrease relative to previous projections as a result of the Supreme Court decision.

Laboratory Reimbursement

We have heard concerns from laboratories that they have not been paid for molecular pathology services performed since January 2013. We understand that CMS is currently making adjustments to the payment methodology for these services.

9. However, is the agency considering options for ensuring that these laboratories will be paid for prior services in the near term?

Answer: CMS regularly uses Current Procedural Terminology (CPT) codes developed by the AMA in establishing payment rates for Medicare services. The AMA CPT Panel developed 114 new CPT codes for CY 2012 and CY 2013 to replace multiple "stacking codes" (based on component steps) that were previously used to bill for molecular pathology tests. The old "stacking codes" were deleted at the end of 2012 and are no longer available.

The majority of the new codes were issued for CY 2012, but CMS decided to delay their use for a year to carefully consider whether they should be paid under the physician fee schedule (as physicians preferred) or the clinical laboratory fee schedule (as preferred by laboratories). After requesting comments as part of the CY 2013 physician fee schedule proposed rule, we finalized a policy to pay for these codes under the clinical laboratory fee schedule, with an additional payment available for interpretation by a physician under the physician fee schedule.

New rates for these tests are being established through the "gapfilling" process, which enables the local Medicare contractors to use a wide range of relevant data to determine payment amounts for these tests. CMS will then use the contractors' gapfill prices to set "national limitation amounts" for these tests. The contractors' prices were submitted to CMS in April and will be posted on the CMS website in May and open for public comment for a 60-day period. CMS will post final payment amounts in September, at which point stakeholders have 30 days to request reconsideration. The 2014 clinical laboratory fee schedule, including national limitation amounts for the new test codes, will be issued in November.

While this process is underway, these molecular pathology tests are being paid at interim rates set by the contractors, which may reflect invoice amounts, the previous price amounts known as "stacking codes," or case-by-case determinations by the contractor medical directors. CMS has asked laboratories to bring to our attention any areas where the Medicare contractors have not taken action on submitted claims. As indicated above, a 60-day public comment process is currently underway on the prices proposed by the contractors. We urge laboratories to bring cost information to our attention to assist with final pricing of these services over the next several months. As we obtain more information on the costs of these services from laboratories, we are optimistic that we will be able to establish prices satisfactory to both Medicare and the laboratory industry.

10. Please outline the specific efforts HHS has taken to ensure stakeholder feedback was sought as this new payment methodology is developed.

Answer: CMS follows the process set forth in the statute for establishing payment rates for new test codes. In the case of the new molecular pathology test codes, payment rates are being developed through gapfilling, as described above. This process includes multiple opportunities for stakeholder involvement including (1) input to the local Medicare contractors to inform their development of proposed gapfill payment amounts; (2) a 60-day public comment period on the proposed gapfill payment amounts; and (3) a further chance to request reconsideration of specific rates after final payment amounts are posted in September by CMS. Information on the current 60-day public comment process is available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Gapfill-Pricing-Inquiries.html.

Senators Menendez and Portman

Medicare Part D

Madam Secretary, We wanted to follow-up with you on our conversations during the hearing about the president's proposal to require Medicaid-style rebates in the Medicare Part D program for beneficiaries who receive the Part D Low-Income Subsidy (LIS). As we both mentioned, the Part D program has shown to be quite successful over the last several years in providing stable costs for beneficiaries and lower than projected costs to the government. Specifically, we both noted – and you concurred – that beneficiary premiums have been flat for the last three years and the program has not only come in at 40 percent less than originally estimated, but that the Congressional Budget Office has lowered the future spending estimates by $100 million a year for the last three years. Given these facts we want to ensure that such a major change to the program doesn't undermine the program's successes, which would ultimately lead to beneficiaries being worse off.

The Part D program already has policies in place to provide low-income beneficiaries with cost-sharing subsidies and other cost reduction assistance. In fact, most beneficiaries in the LIS program pay no monthly premium and do not have a deductible. While we share the goal of reducing costs to beneficiaries, especially lower-income beneficiaries who might not otherwise be able to afford their medication, we want to insure that any rebate actually benefit these beneficiaries.

1. **Please provide us a detailed analysis of how the proposed rebates in the Part D program will lower costs, or otherwise benefit, the LIS population for which they would apply.**

    a. **Please include estimates of the future costs (including premiums, deductibles and co-pays) these beneficiaries might experience under this proposal and how those future costs compare with both current costs and estimates of future costs under current law.**

Answer: The Part D Low Income Subsidy program was created to provide extra help with prescription drug costs for eligible individuals whose income and resources are limited. The methodology to calculate premium subsidies and the copayments for brand and generic drugs are set by statute and do not change under the rebate proposal. As a result, beneficiaries receiving the Low Incomes Subsidy should not experience any change in out-of-pocket costs for prescription drugs. However, the federal government and, as a result, taxpayers, will see substantial savings if this proposal is enacted. These price concessions, or rebates, are the same rebates that the Medicaid program currently receives from manufacturers. This proposal is an important way that the Federal government can reap savings on the drugs provided to beneficiaries who are eligible for Medicare and Medicaid and others who receive the Part D Low Income Subsidy.

The LIS population comprises roughly 30 percent of Part D enrollees, when factoring in those with a partial LIS subsidy, the full LIS subsidy and the Medicare-Medicaid dual eligible population.

2. **Please provide us a detailed analysis showing the impact this proposal would have on the 70 percent of Part D enrollees who are not currently eligible for LIS. Please include estimates of the future costs (including premiums, deductibles and co-pays) these beneficiaries might experience under this proposal and how those future costs compare with both current costs and estimates of future costs under current law.**

Answer: The Part D program is working well and providing valuable savings to seniors and people with disabilities with their prescription drug costs, particularly for dually eligible Medicare-Medicaid beneficiaries who automatically receive subsidies from the government for their premiums and copayments. Given the fiscal challenges our country faces, however, Medicare must continue to find ways to ensure the program is providing the best value to beneficiaries and taxpayers. The Part D Low Income Subsidy is the largest component of Part D spending, totaling $22.8 billion in 2012. These price concessions, or rebates, are the same rebates that the Medicaid program currently receives from manufacturers. This proposal stems from a recommendation by the bipartisan National Commission on Fiscal Responsibility and Reform and reinstates savings that taxpayers previously received when dually eligible individuals received their drug benefit through the Medicaid program. This proposal does not directly modify beneficiary cost sharing or premiums, and the future costs that beneficiaries may face will vary based on numerous factors, including pharmaceutical manufacturers' pricing decisions in response to legislative changes.

3. **One of the concerns we have with this proposal is the effect it would have on prescription drug plan formularies. Specifically, we are concerned with the possibility that prescription drug plans will alter their formularies to limit the number of drugs on the lower-cost "preferred" tier, push more drugs into the higher-cost specialty tiers or remove coverage for some drugs altogether. Any of these outcomes would have a substantial negative impact on beneficiaries. Senator Menendez asked you directly if this plan would have an impact on formularies and you said it would not.**

Please provide us with the data and analysis used to definitely determine these rebates will not affect plan formularies, including how the proposed rebates will not: impact the type and number of drugs available on all plan tiers (including any shifting of drugs from preferred to non-preferred or specialty tiers or removing them from the formulary entirely); alter out-of-pocket costs; and restrict access to pharmacies.

Answer: Robust competition leads to better prices in the Part D program, and competition will remain strong under this proposal. Competition within drug classes will remain intact. Manufacturers will still have an incentive to offer rebates to plans, because that will allow them to have their drug placed on a preferred coverage tier in the plan's formulary, which will provide access to the drug for beneficiaries and savings for taxpayers. This proposal is an important way that the Federal government can reap savings on the drugs provided to beneficiaries who are eligible for Medicare and Medicaid.

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